Spire™
INSPIRING RESPIRATORY HEALTH

ZAN300 CO Diffusion

Operations Manual

Part Number : 5001003ENG

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www.nspirehealth.com

Manufactured for	**nSpire Health Inc** 1830 lefthand Circle, Longmont, Colorado, 80501, USA	Tel: 1.800.574.7374 Email: **sales@nspirehealth.com**
Authorized Representative	**nSpire Health Ltd** Unit 10, Hartforde Court John Tate Road Hertford, SG13 7NW U.K.	Tel: (+44) (0) 1992.526.300 Email: **info@nspirehealth.com**
	nSpire Health GmbH, Schlimpfhofer Strasse 14 D-97723 Oberthulba Germany	Tel: (+49) 097.36.8181.17 (+49) 097.36.8181.27 Email: **zan@nspirehealth.com**

Dear Customer,

Thank you for purchasing the Flow Handy ZAN300 CO Diffusion System.

The product complies with the newest state of technical development. In order to improve the lifetime of this product, only materials of extremely high quality are used. All materials are environmentally safe and can be recycled.

The manual provides instructions for operating the ZAN300 CO Diffusion system.

The instructions in this manual assume the user is familiar with the intended use and application of pulmonary laboratory systems.

To avoid damage to the devices or incorrect measurement, it is strongly recommended to follow the instructions in the manual and the technical description.

Your nSpire Health-Team

nSpire Health GmbH

Schlimpfhofer Str.14
97723 Oberthulba/Germany
Tel. +49 9736 8181-0
Fax +49 9736 8181-20

E-Mail: info@nspirehealth.com
Web: www.nspirehealth.com

CE 0535

Documentation Conventions

The following format conventions are used in this document to identify special information:

Warning: statements identify conditions or practices that could result in personal injury.

Caution: statements identify conditions or practices that could result in damage to equipment or loss of data.

Note:	**The graphical illustrations in this document are for example purposes only and the hardware illustrated may differ from your hardware.**

Safety Precautions

The ZAN hardware has been tested and certified to be compliant to UL 2601-1 and CAN/CSA C22.2 NO. 601.1. Type I equipment electric shock protection is provided by 3-wire power cord earth ground and additional external earth ground as described. However, the following precautions must be observed for auxiliary equipment:

a. Connect the power cord for each individual component to a wall source.

b. Do not connect extension cords to the system.

c. Do not use multiple power strips; and only use the power strip that is supplied by nSpire Health.

d. Operate the hardware device only when the power cords are plugged into "U" grounded outlets (3-hole outlets).

e. Unplug the power cords prior to servicing the equipment.

f. Computer, monitor, printer, and testing unit are components fit for use within the patient environment, provided external grounding has been implemented as per instructions.

g. The User/Operator must not touch any non-medical device (that is, any device other than the testing unit) and the test subject at the same time.

h. The ZAN hardware (ZAN100 USB) has been tested and meets the latest EMC requirements for immunity and emissions of IEC 60601-1-2. However, electromagnetic interference may still be encountered. If the device is behaving erratically due to electromagnetic interference, contact nSpire Health customer support.

i. Do not connect items that are not specified as part of the ZAN hardware (ZAN 100)

j. Do not operate the ZAN hardware (ZAN300 CO Diffusion System) or other system components on any voltage other than that specified.

k. All flammable materials must be kept away from the equipment and “No Smoking” signs must be prominently displayed in the testing area.

l. Oil and grease must be kept away from oxygen equipment.

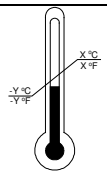
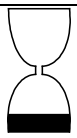
m. Oxygen-approved regulators must be used for O_2 tanks.

n. The equipment is a Type IIA device that requires the use of a 3-wire Type I cord-set.

Warning: For Denmark, it is extremely important not to use the Schuko CEE 7/7 plug; it will mate with the Danish socket, but it will not be grounded. This may result in serious safety hazards.

o. According to good hygiene practices, filters and/or mouthpieces that came into direct contact with the subject's mouth or aerosolised droplets from the subject's effort should not be touched. Dispose of filters and mouthpieces as ordinary waste, or as specified by your institution.

Labelling Glossary

Glossary of Common ISO Symbols[1]			
	High Voltage		Item for single use (do not use more than once).
	This symbol indicates that the user must read and understand all instructions and warnings prior to use.		Acceptable Ambient Temperature Range: Indicates the upper and lower temperatures allowed for transport and storage.
	Protective earth ground		Indicates the date by which the product must be used, in the format Year.Month.Date (e.g., 2005.02.19)
	Type B Equipment: Equipment providing a particular degree of protection against electric shock, particularly regarding: allowable leakage current and reliability of the protective earth connection (if present).		Heavy weight.
	Alternating current		Fragile.
	Direct current		Keep Dry.

[1] International Standard, CEI IEC 417P, Graphical symbols for use on equipment, first edition, 1973

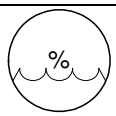
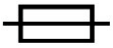
Glossary of Common ISO Symbols[1]			
	Power on		Transport and storage humidity conditions.
CE 0535	This symbol indicates that this Class IIA equipment complies with the guidelines concerning medical devices 93/42/EEC of the council from 14.Jun 1993.		Power off.
	Fuse		This symbol indicates that the associated jack is for a USB (Universal Serial Bus) connection.

Table of Contents

1 General Information on ZAN300 CO Diffusion

The ZAN300 CO diffusion medical product is a PC-based measuring system for the determination of the diffusion capacity of the lungs. The PC and the CO diffusion electronic system are connected via a USB interface.

The main field of application of ZAN300 CO diffusion is in the clinical area of pulmonary function testing and pulmonary specialists.

All possible measurements can be seen in the table of contents of this manual.

Important: For using this device for the measurement of patients, the user has to receive comprehensive introduction to the handling of the device and be able to prove this towards the responsible authorities and test centres.

The manufacturer or the authorised specialist dealer supplies this device together with comprehensive introduction only. To this effect, this user manual is always used as a training document. The operator is responsible for seeing that each user receives a corresponding introduction and thoroughly studies the manual. Furthermore, the user should be ale to prove corresponding specialised medical training.

The operator is responsible for the professional and appropriate handling of this device.

The software running under MS Windows is delivered together with the measuring device.

From simple spirometry, pre/post comparison, trend analysis as well as CO diffusion measurement, the measurement program includes all common requirements by default. Moreover, a large number of options, such as for example hyperreactivity evaluation or P0.1 measurement, are offered.

An easily understandable user interface ensures a short training period. The programme structure offers ease of use.

The standard value equations of various authors of reference values are pre-set, additionally other standard values can be added in the form of equations.

Drug lists can be predefined and completed at any time.

Archiving of patient data and measurements is integrated. The system is network-compatible.

Data transfer to practice computer systems is achieved via the formats BDT, GDT and HL7.

All measuring results and graphical data can be viewed on the screen. Log output to the printer is carried out through the log interface of MS Internet Explorer®. Nearly any curve can be measured manually through tangents adaptation, both directly after the measurement and after archiving.

Attention The option ZAN300 CO diffusion must only be operated in conjunction with a ZAN 252 or ZAN 260 system trolley, otherwise the safety of ZAN300 CO diffusion may put at risk.

Plug connections must only be used for the components of nSpire Health described in this user manual.

1.1 The software

The supplied software GPI3.00 includes patient data management, measuring and calibration programmes and a database for the measured values.

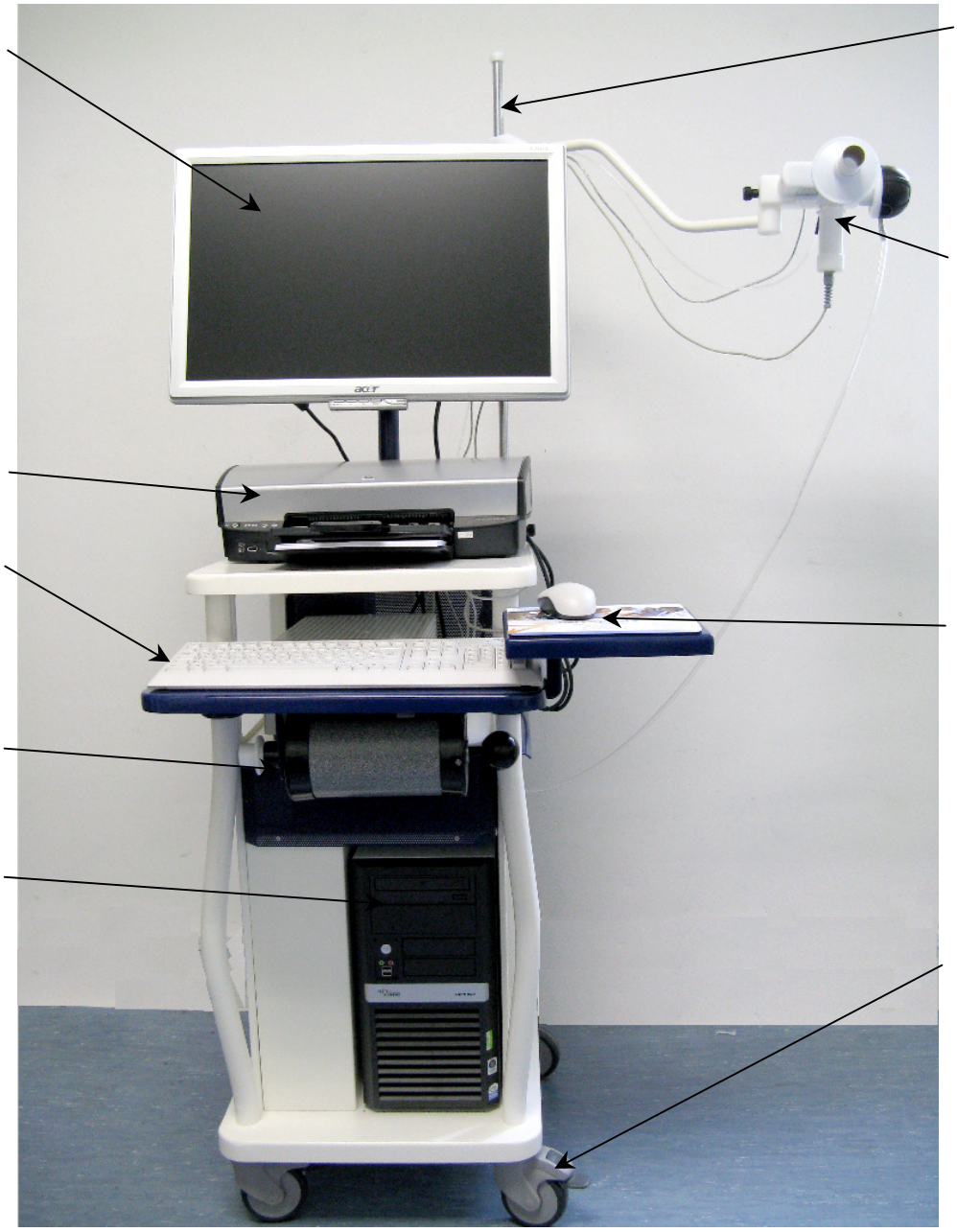
The archived data and measurements can be called up and printed at any time.

1.1.1 PC System Requirements

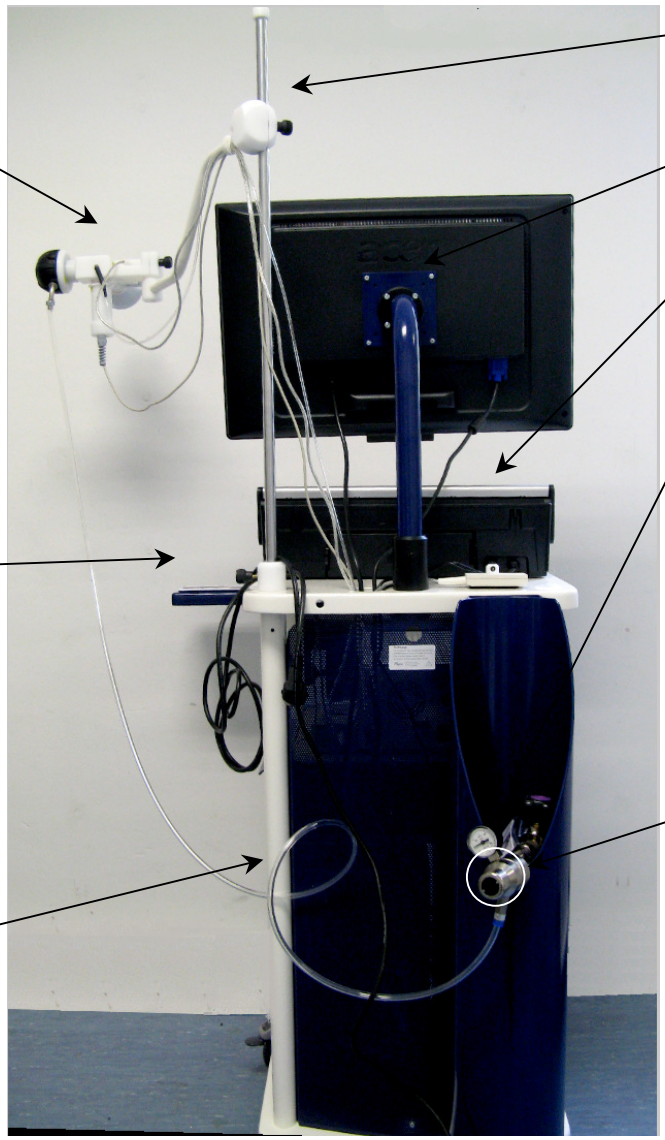
Minimum Requirements

Operatingsystem	WIN 2000, WIN XP
CPU	Pentium IV, 1.89 GHz or better
RAM Size	500MB
Hard disc	40GB
Installationdrive	CD-ROM
Device interface	USB 2.0
Monitor:	19“ Colour monitor
Screen resolution	1280x1024 Pixel or better
Printer	colour

1.2 Overview

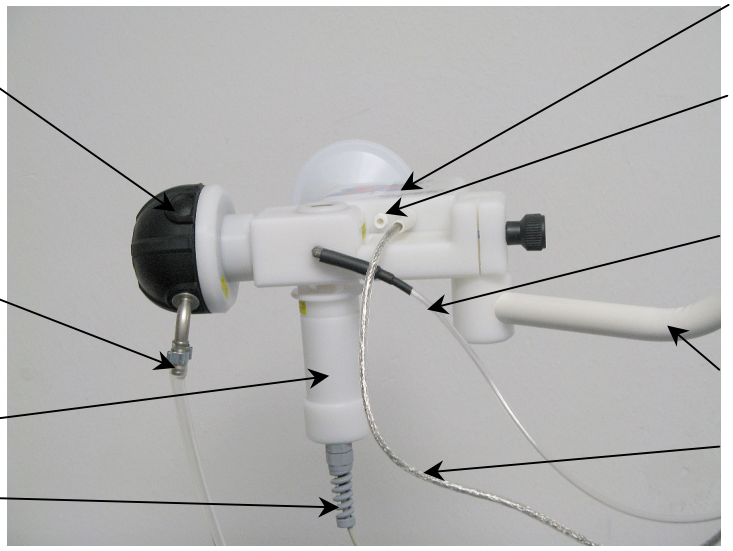


front view

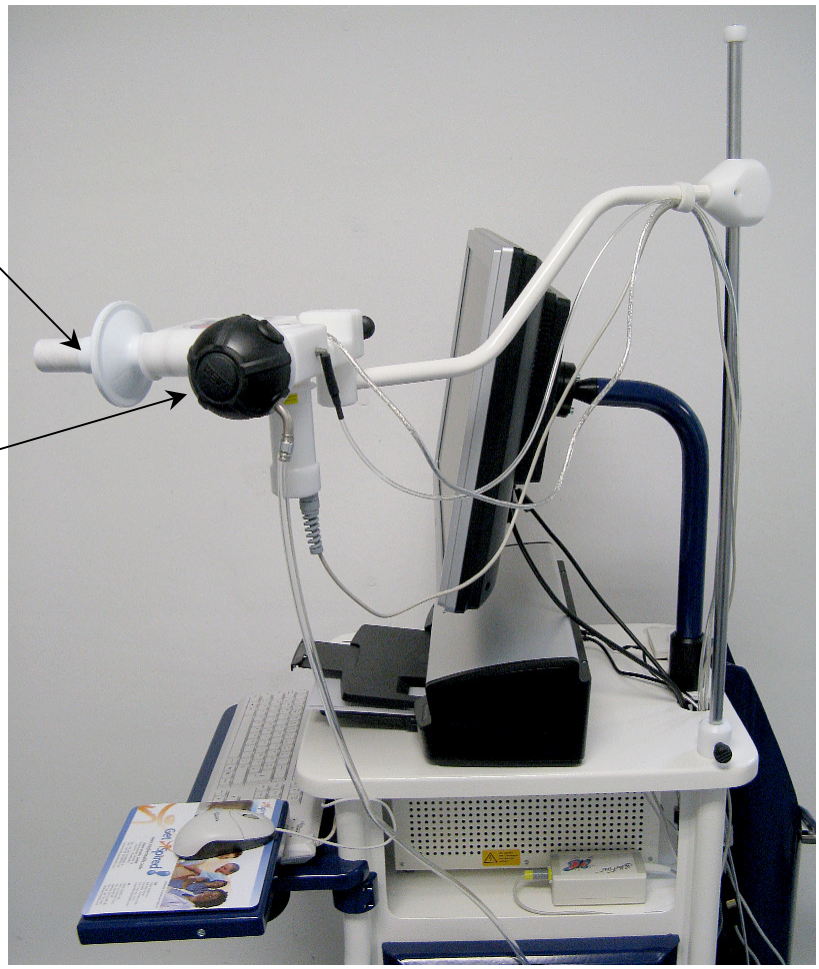


Tube connection onat the pressure reducer. By pressing the blue ring and simultaneously pulling the tube, the tube can easily be disconnected **in unpressurised** condition.

Rear view with cover

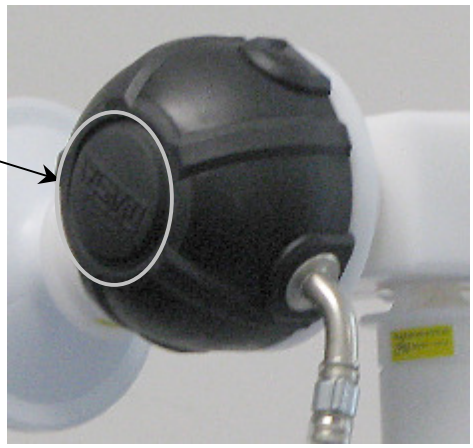


Rear view of measuring head

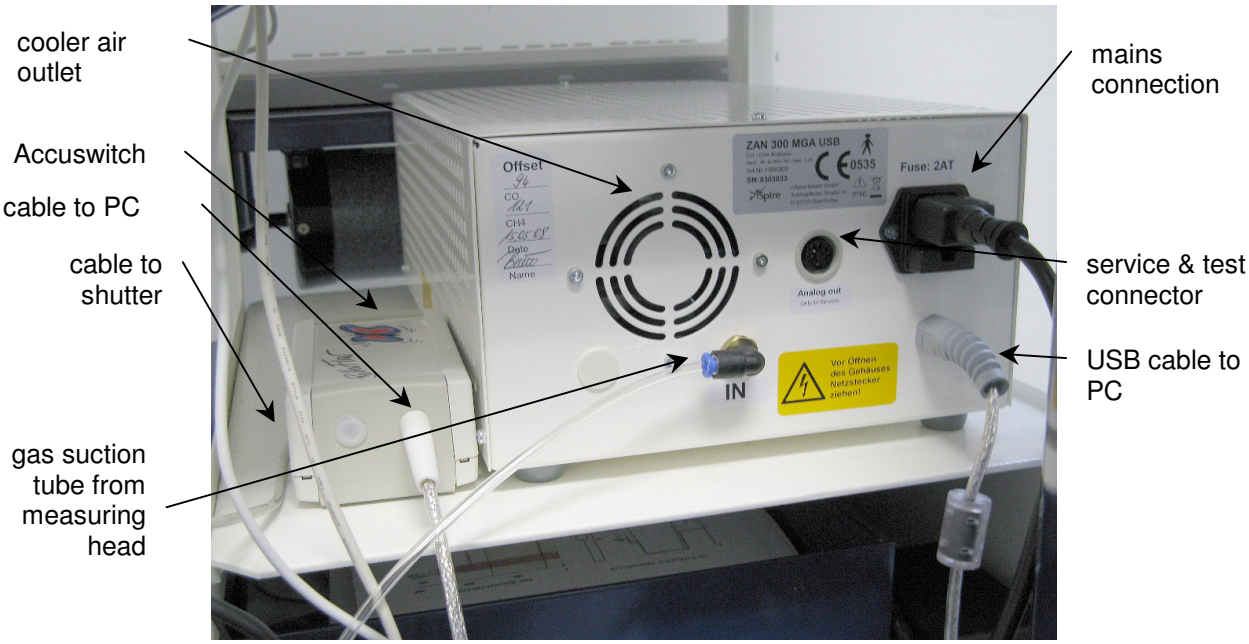


Side view

The figure shows a normal breathing apparatus for use as a “standalone“ version. For the CO diffusion option of the ZAN Body Plethysmograph, another breathing apparatus (with blocking magnet) is used. The two components are not interchangeable.



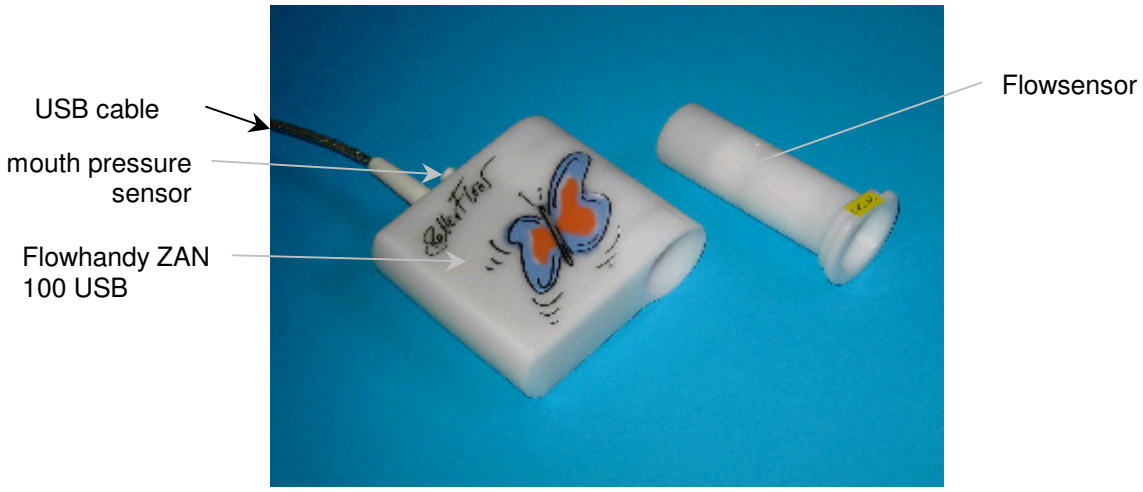
The hand-operated button is located on the rear side of the breathing apparatus, it is integrated into the black cover. It has to be used for venting the system when changing the gas cylinder or for removing the breathing apparatus for disinfection.



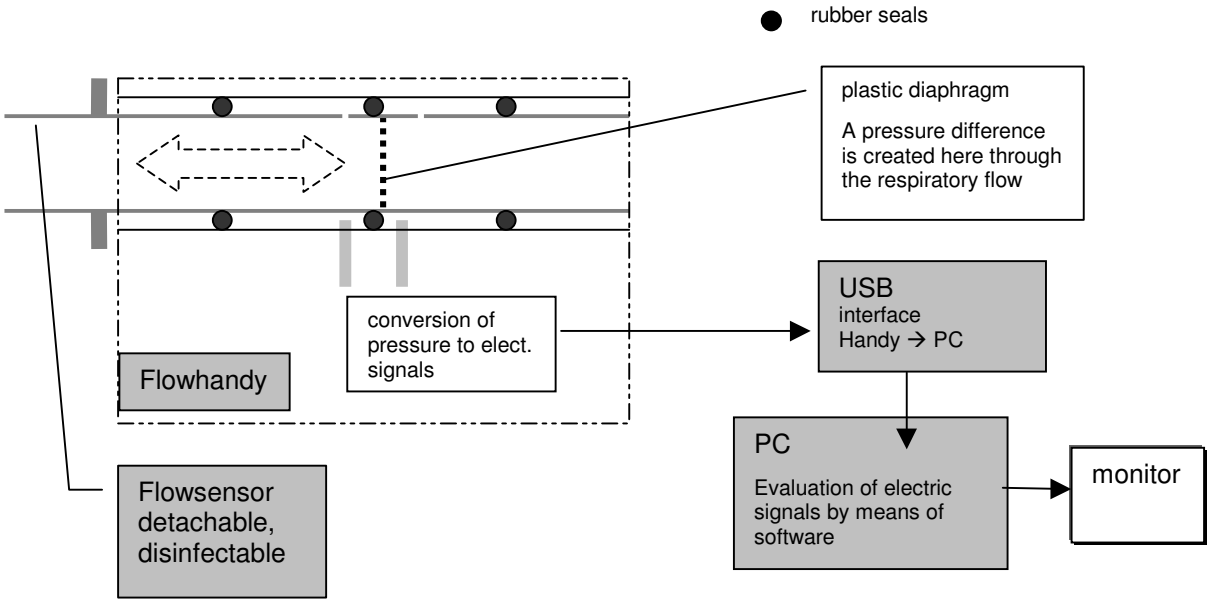
Rear side of ZAN300 measuring device without cover

The rear cover normally does not have to be removed. There are no parts or switches to be operated by the user.

1.3 The Flowhandy ZAN 100 USB



1.3.1 Functional diagram of Flowhandy ZAN 100



1.3.2 The Flowsensor

The sensor works on the principle of turbulent flow measurement based on pressure difference. To this effect, a plastic diaphragm with variable orifice is used as flow resistance.

The sensor works silently and is absolutely insensitive to the humidity of expired air. The resistance of the diaphragm is very low so that no additional breathing load is created. The patient will feel the result of these details.

Even patients with breathing difficulties can breathe on the system

- without noticeable CO2 rebreathing
- without noticeable resistance.

1.3.3 List of parameters for spirometry and F/V measurement

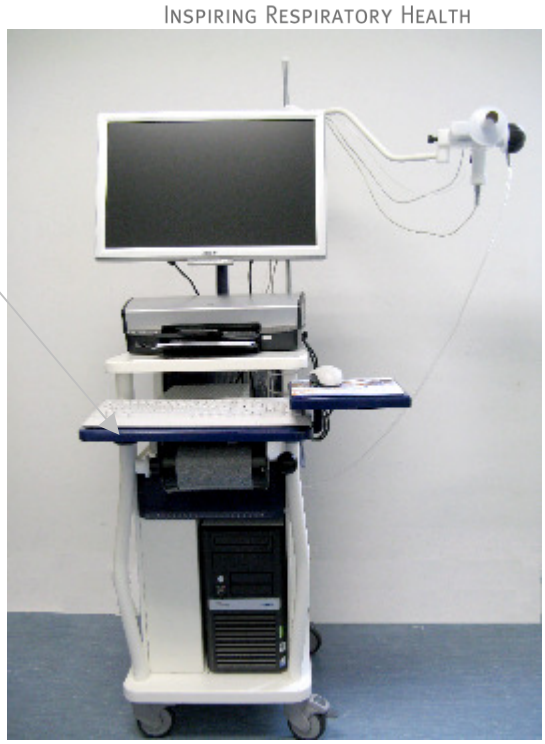
IVC	ERV	IRV	TV	FEV1	FVCin	MEF50/FVCex	FEV1/IVC
FIV1	MEF25	MEF50	MEF75	PIF	FVCex	MEF75/FVCex	FEV1*30
Aex	MIF25	MIF50	MIF75	MIF75	Ain	PEF/FVCex	MEF75-85
PEF						FEV1/FVCex	MEF25-75
Rocc for option Rocc							MEF25/FVCex

1.4 The ZAN 260 system trolley.

The two boxes ZAN310 and ZAN610 and the peripheral units are accommodated on this system trolley.

The trolley offers space for a PC, a printer and a flat screen, as well as for gas cylinders, stands and small accessory.

main switch



1.5 Special instructions for use

Note: Please pay attention to the notes on safety in the chapter “Safety” as well as the notes on cleaning and disinfection in the chapter "Disinfection".

Important: Only use bacterial filters such as KoKo Moe filters or filters approved by nSpire Health.

1.6 Initial commissioning

Before commissioning, the software has to be installed on the PC. The description as well as a system check are included in the annexe.

If something does not work straightaway, you can find important tips in the chapter “*What to do when*“.

Note: For obtaining accurate measurements, the user has to be familiar with the handling of the measuring device. Furthermore, he/she must have studied the user manual and therefore know all about the safety and measurement procedures.

1.7 Hygiene

As a general rule, an appropriate level of hygiene has to be ensured when handling contaminable components.

All contaminable components can easily be taken apart and disinfected.

Instructions on how to do that and suitable methods and means can be found in the chapter Disinfection.

1.8 Special actions before daily starting-up

As a general rule, the gas analysers have to warm up **for at least 30 minutes** before a calibration or measurement can be started.

The overall system should be calibrated at least before the first measurement of each day. The calibration procedure is described in the corresponding chapter.

2 User interface

The ZAN GPI 3.xx software interface is designed for ease of use. The list of patients and the measurement results are shown in the form of an 'index' card (tabular form) on the screen.

There are 4 programme modes: **Patient Mode**
Measure Mode
View Mode
Archive Mode

The visible 'index card' lets you handle the data sets of up to 5 different patients simultaneously. You can switch to single patient mode using the set-up [alt/S].

The number of patients in the archive is only limited by the capacity of your hard drive.

Software navigation is simplified by using the buttons on the right hand side of the screen allowing quick access to entering patient biographical data, for performing tests with the measure button, to view results of tests performed today (or in the past) and to archive the results to the database.

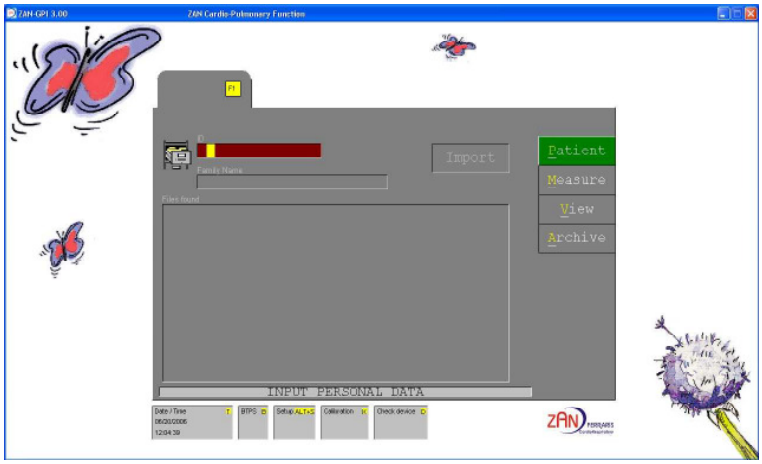
Note: 'To click on' or 'select' means to move the cursor over the desired button and then press shortly the **left** mouse button.

You can also select an option with the keyboard. Use the yellow coloured characters to activate the desired option.

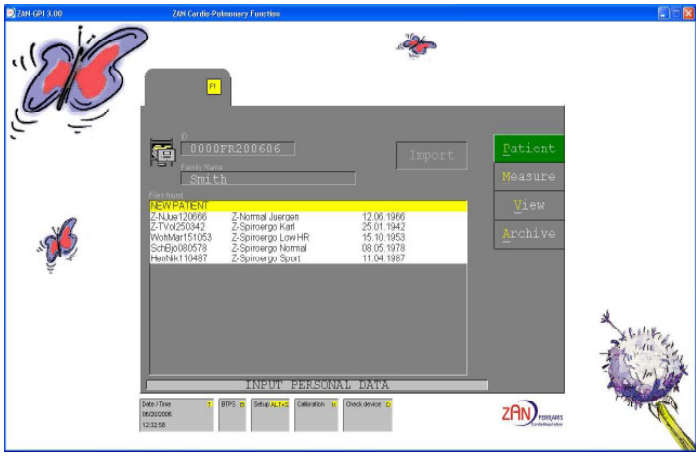
2.1 Activating the Programme

After successful installation, clicking on the ZAN icon  on your desktop activates the programme.

You see the index card →



2.2 Patient Data Entry



Select a blank tab form either with the mouse or the keyboard and enter the surname (just the surname without any add ons). Press the [enter] key.

The system will now check the database to see if this name has been stored before.

If so, you will see a list of all patients with this name. Additionally this list contains an entry "NEW PATIENT".

Using the mouse or the arrow keys, you can select a patient or the "NEW PATIENT" Option to enter a new one. Press the [Enter] key to confirm the selection.

If you select "NEW PATIENT", an input form appears.

Each field should be completed with the relevant data and confirmed with [Enter]. The cursor will automatically jump to the next field.

Accurate patient biographical data is crucial for the calculation of reference values.

It is important to ensure the correct format is used for each field. If the wrong format is used in the date of birth field (correct format: MM/DD/YYYY), it must be corrected to continue

Note: If all Tab forms are in use, use the 'Archive' option to free one.

2.2.1 Input Formats

Field	Format	Remark
Family Name	All letters	The first 3 letters are used for an automatic ID number.
First name	All letters	The first 3 letters are used for an automatic ID number.
Date of birth	MM/DD/YYYY	Month/Day/Year. Leading 0 does not have to be entered, but the slashes between the dates are required. The input of century or millennium can be left out, if the patient's age is below 100.
Height	in.	Input is limited between 20 and 100.
Weight	lbs.	Input is limited between 2.2 and 551.
Sex	Selection with arrow keys	← → or with the mouse
Comment	All letters	Free form text.

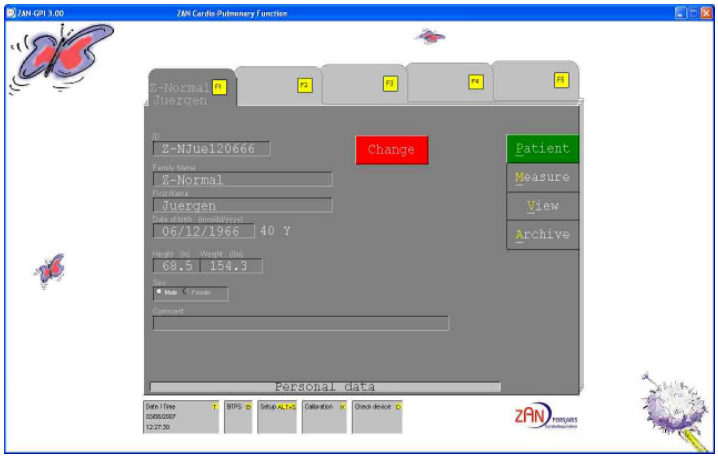
Caution: If the cursor does not leave the input field, it is likely the input format is wrong. This happens frequently in the date of birth field, but check all data fields for format errors anyway.

Once all fields are completed, the record can be saved using the save button. 

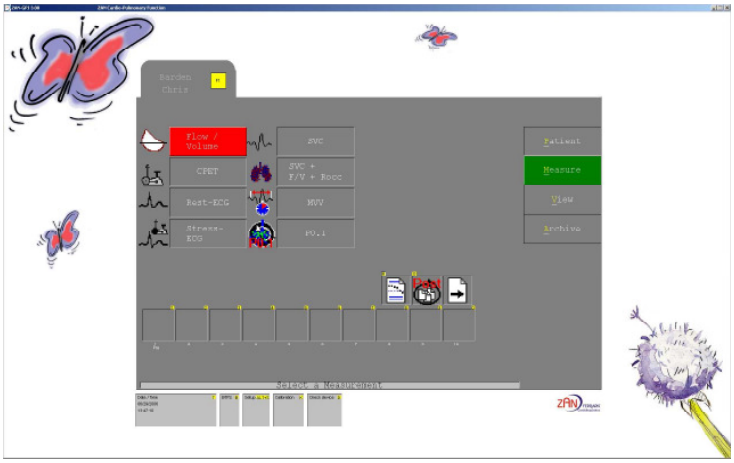
Caution:

If the cursor jumps into the **ID-No.** field, this indicates that the automatically determined ID-No. has already been assigned to another patient. As patient data must be differentiated, the ID-No. must be modified manually.

Press the save button again.



The patient's name will appear at the top of the index card. The system is now ready to begin testing.



2.3 Modifying Patient Data

From the measurements screen, click the Patient button to open the patient data field for the current patient.

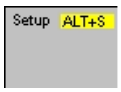
Once the patient file is open, the Change button will become available. Click this → to enable changes to the patient data file.

After the desired changes have been made to the data, select the Save button.

Note: Archived data can also be modified in this way.

2.4 Entering Additional Patient Data (Optional)

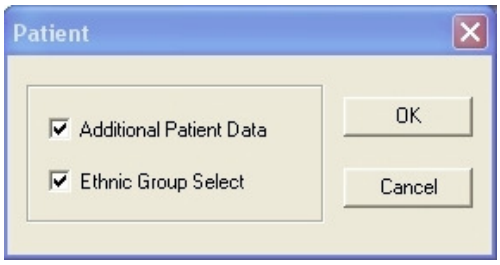
This option can be selected to add additional patient data for each patient.

Access the Set-up menu using this icon 

(located at the bottom of the screen). From this menu, select Patient.

Note: This is password protected and should be set up by your representative during installation. Please contact your representative for further information.

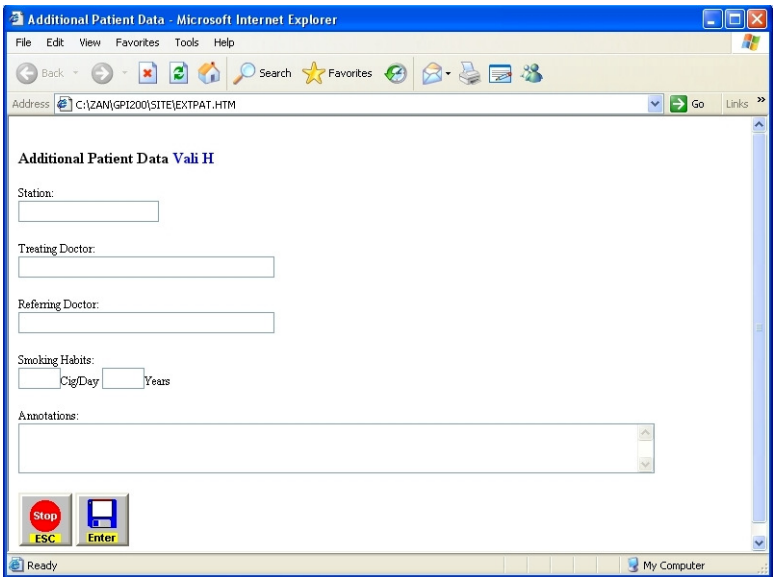
On the Patient dialogue box, click the Additional Patient Data checkbox.



Once the required selections have been made, the ZAN software must be **restarted** for the desired changes to take effect.

Once the additional patient data has been activated, it will be available within the patient data screen. By clicking on the Extended button,

the Extended Patient data screen is then opened and can be completed in the same way as the Standard Patient data screen.

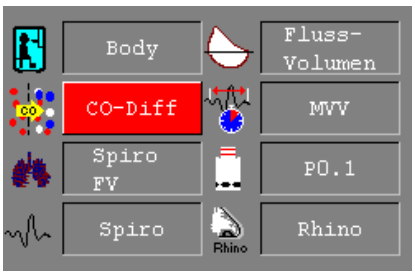


When the required fields have been completed, select the [Enter] key to save this data.

2.5 Measurement Mode

Once the input of Patient data is complete, measurements can be performed on the active patient. Select the Measure button from the menu or press [M] to display the measurement mode screen.

Select the required test.



Note: The options available on this menu will vary according to the installed components and hardware.

2.5.1 Symbol Definitions

before a Measurement

Cancel the measurement

Shutter test

Zero the flow sensor (Patient must not breath into the flow sensor !)


zoom in


zoom out

choose medication

identify current user

Notes

display the incentive graphs. With each click, the incentive graph changes to a new selection.

Start measurement

during a Measurement

delete previous recordings and go on with the measurement

delete FV loop on screen

Shutter test

Zero the flow sensor (Patient must not breathe into the flow sensor !)

Activate Shutter for Rocc test

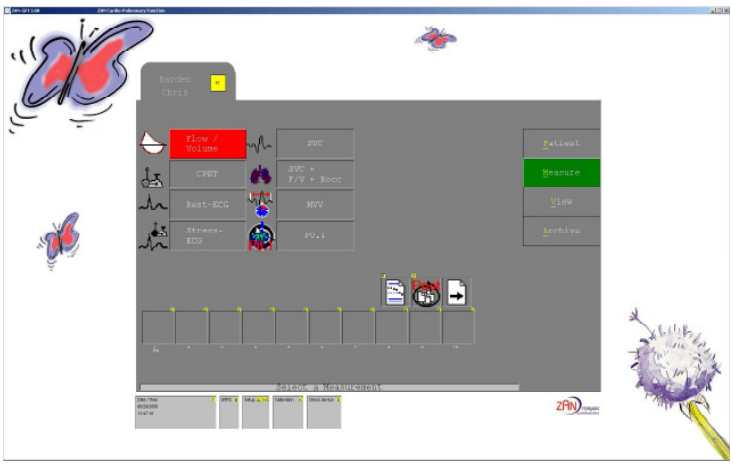
save and terminate

Select the measurement programme using the mouse or the arrow keys ← →

The programme is selected, when the corresponding field is displayed in red.

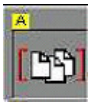
The measurement programme starts either when you click on the selected field again or by pressing the[Enter] key.

Refer to the corresponding chapters for explanation of the particular measurement programme.



Once the measurement is completed, all tests can be reviewed, compared, and printed under the View mode by clicking the View button or pressing the [V] key.

2.5.2 Symbol Definitions


automatically select best curve


print report on screen


change pre-, post assignment


show tests from the first on


print report


change position


provocation test (optional)

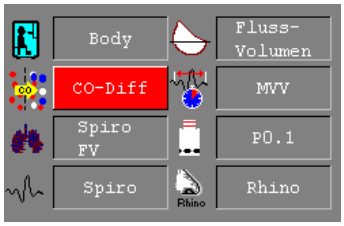

enter remarks

delete measurement

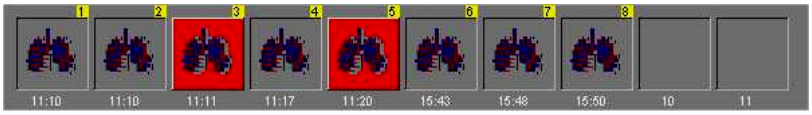

show more tests (>10)

2.5.3 Review measurements of the day

After selecting the measurement type, all measurements of this type, taken on this day are displayed.

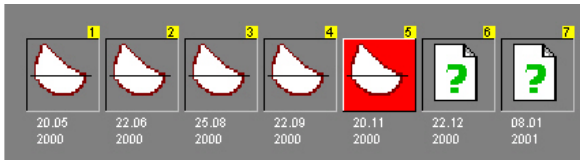


Click on the appropriate field to select one or more from the list and display them on the screen.



2.5.4 Displaying Archived Measurements

To view measurements performed previously (week, month, or year) on the same patient, access the archive folder with the Archive button or by pressing the [-] key.



Archived measurements are displayed in fields 1-10, labelled with the date on which they were performed.

The question mark (?) indicates that on this day the patient folder has been opened, but the measurement has not been performed.

Select a date with the mouse and 'close' the archive by pressing the [+] key.

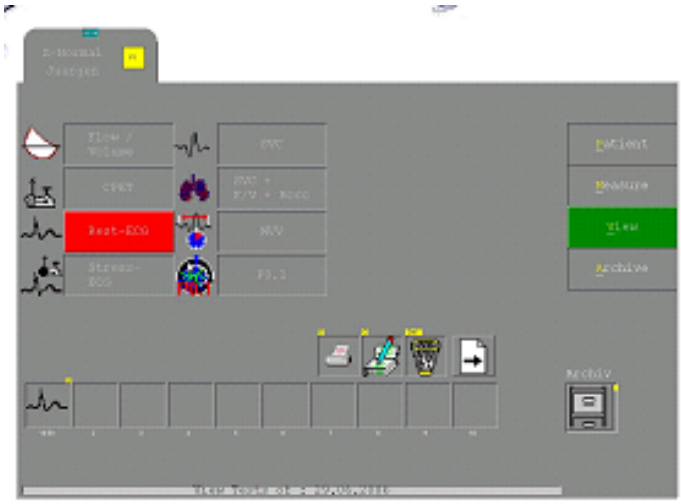
A list of all measurements on this day, labelled with their time, shows up.

Select the measurement, you would like to see.

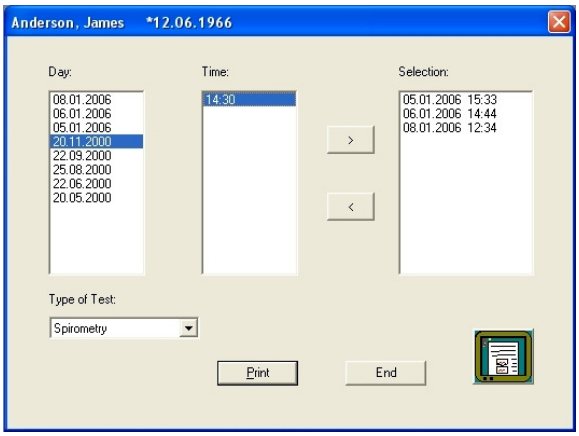
Then click on  to select the desired report type and press **[ENTER]** to print the report.

2.5.5 Comparing Measurements of Several Days

From the Archive menu it is also possible to compare measurements that were made on different days. This is achieved by double clicking on the Days to Compare Button



This opens an options box.



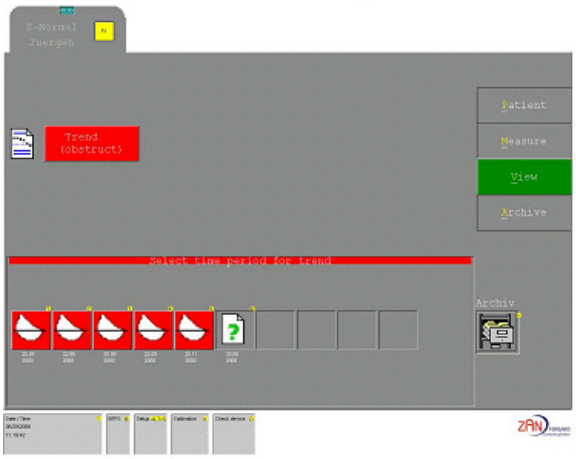
This options box enables the user to select tests from a specific day and time to be included in the comparison. Tests can be moved into the Selection Window using **[>]** (or removed with **[<]**).

The type of test for comparison may be modified by using the drop down menu in the bottom left corner. When the desired tests have been selected, the print key will print these results to the local printer.

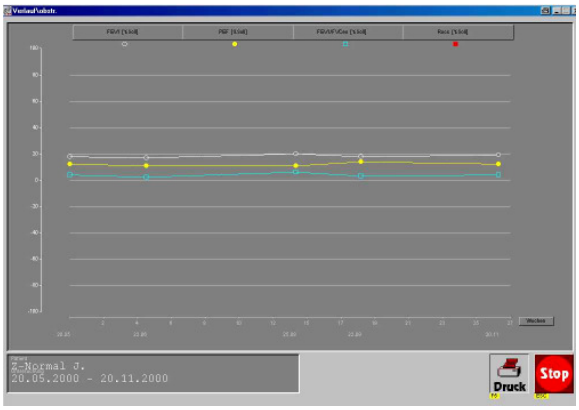
The print preview option opens the report in Microsoft Internet Explorer® for viewing on screen and this will also enable changes to the printer set-up.

2.5.6 Trend Graphs

From the Archive menu it is possible to create a Trend graph for either restrictive analysis or obstructive analysis using one of the Trend buttons.



After clicking on the Trend button, a window is displayed that enables the selection of multiple tests for trending analysis. Once the desired tests have been selected, it is possible to view the trend graph by clicking the Trend button or pressing [Enter]. See Trend graph screen on next page.



Trend (restrict) creates a trend of Static Lung Volume values VC, TLC, RV, and RV/TLC.

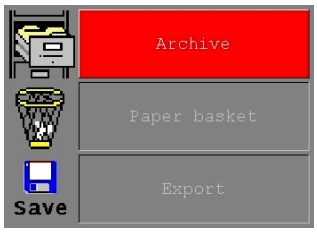
Trend (obstruct) creates a trend of spirometry values FEV_1, PEF, FEV_1/FVC, and ROCC.

2.6 Archive or Delete Files

From this menu the user is able to perform the following functions on the entire patient file:

Archive: Automatically archives the entire patient file to the database.

Paper basket: Completely deletes the current patient file.



Caution:	If confirmed, this action is not reversible

Export: Exports the complete ZAN patient files to a specified location for import.

2.6.1 Archive

Use the [Archive] option to write your Patient Data to disc.

2.6.2 Waiting Room (optional)

If you use the waiting room option, data is stored in an intermediate storage place. As long as there is data in the intermediate storage, a waiting room symbol will remind you that it is being stored there.

To empty the intermediate storage, select an empty index card, select the waiting room icon and recall one of the listed patients.

Once all patients are removed from the waiting room, the waiting room icon disappears.

2.6.3 Paper Basket, Delete Data

If a Patient folder has to be purged, select the paper basket.

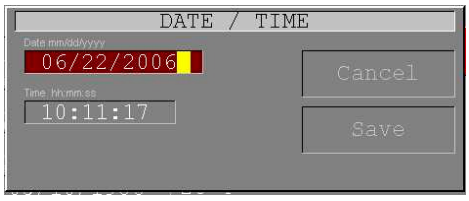
The paper basket option completely deletes the current patient file.

Caution: If confirmed, this action is not reversible.

2.7 Additional Functions

This menu is located below the index card and can be used to alter some of the system settings and other important functions.

2.7.1 Change Date and Time

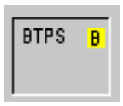


Pressing the [T] key or clicking on the Date / Time box with the mouse, enables the user to change the date and time if necessary.

Ensure that seconds are entered when changing time values!

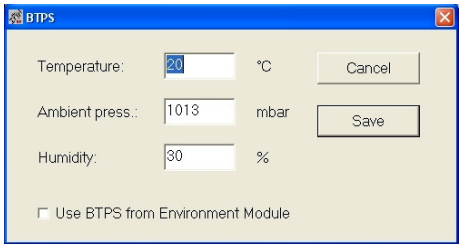
Caution: Ensure the date is adjusted correctly. This could affect a patient's age and the appropriate reference values

2.7.2 Entry of Ambient Conditions



Pressing the [B] key or clicking on the BTPS box with the mouse enables the user to change the values for ambient condition.

*(Only in the Bodyplethysmograph or when using t*he environmental unit, *these data are automatically detected and transferred)*



Caution: Correct temperature adjustment is very important. A mistake of 2 degrees will cause a drift in breathing of about 1 percent.

The absolute barometric pressure must also be entered into the system. Meteorological barometers indicate a pressure, which can be converted according to the sea level.

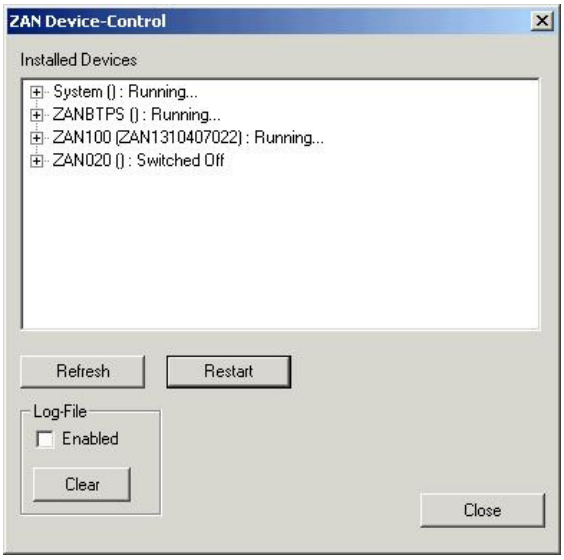
Note: For each 100 meters of altitude, the pressure will lower by 12 mbar.

For Example: The meteorological barometer indicates 1000 mbar at 680 meters above sea level.
1000mbar – (6 x 12mbar) = 1000-72= 928 mbar

2.7.3 Check Device

Pressing the [D] key or clicking the Check Device button opens the check device options box.

This displays a list of the current hardware systems that are running on the current PC (see the following example). It is generally used for troubleshooting purposes if there is a communication problem with the existing system.

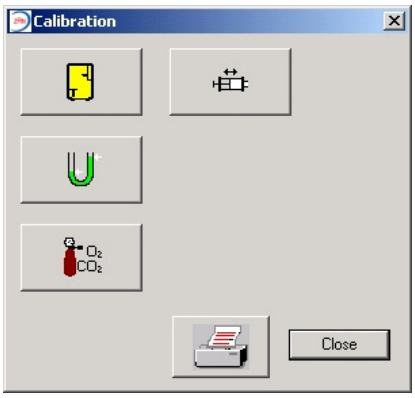


The most important entry in this list is the line: ZAN 100(ZAN1310407022) : Running

This line makes sure, that the Flowhandy is connected to the USB port and active. The numbers may vary and depend on the particular device. However the word 'Running' has to be found at the end of this line.

2.7.4 Calibration

Pressing the [K] key in the menu displays the calibration window. (See also chapter 3.)

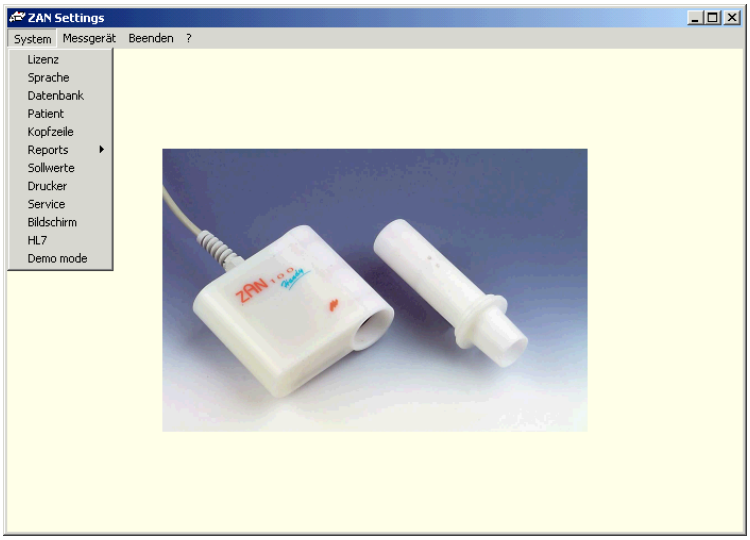


Select the desired programme with the mouse or the arrow keys and start it by pressing the [ENTER] Key.

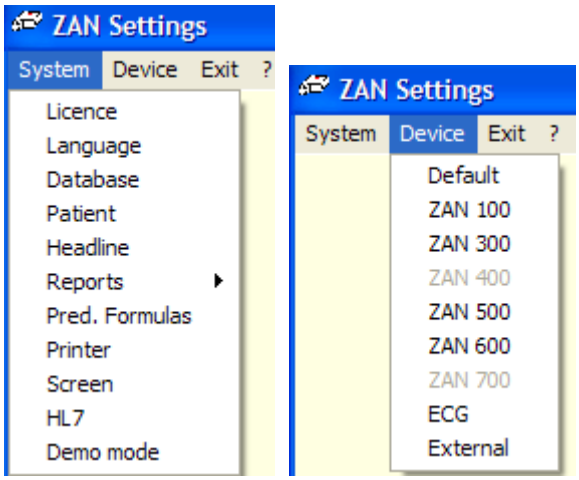
2.7.5 Modify set-up

Pressing [alt/S] or selecting the Set-up button on the base level menu activates the Set-up window.

This Set-up window looks like this:



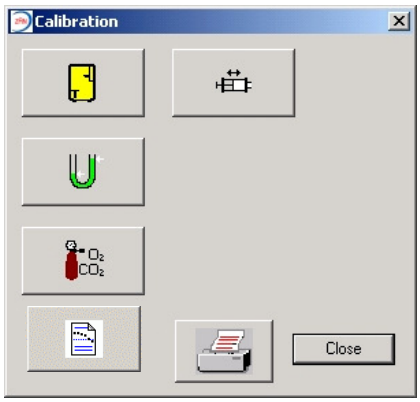
The Set-up Option enables you to set and change some of the programme settings including the following:



A detailed description of these settings can be found in the chapter „Set-up“ (A5) of this manual.

3 Calibration

Pressing the [K] key or selecting the button in the menu, displays the calibration window.



Depending on your license and the included options, the window may have more or less symbols. Only active options are displayed)

Select the desired programme with the mouse or the arrow keys and start it by pressing the <ENTER> key.

3.1 Volume Calibration

Disinfection and use of the flow sensors can change the mechanical quality of the plastic membrane, which is situated on the inside of the flow sensor. The elasticity of the membrane fades and the difference in pressure in front of and behind the membrane will increase. This will affect the accuracy of the results.

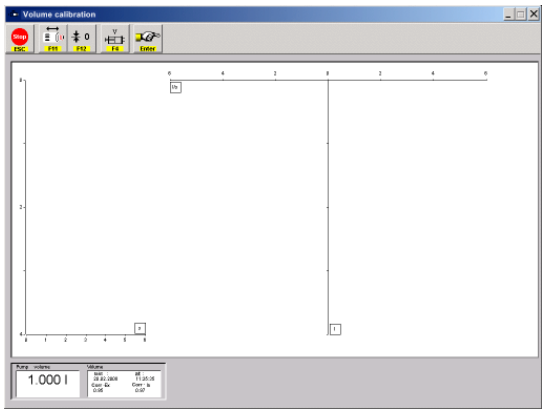
To ensure optimum quality of measurements at any time, a calibration of the system can be performed with the optional available calibration syringe.

Calibration of the Flow Sensor should be done at least after 50 Disinfections, or it should be sent to ZAN for a service. If this is not possible, replace the flow sensor with a new one.

Using filters can reduce the number of necessary disinfections because the filter protects the flow sensor from contamination (as well as the filter protects the patient from contamination through the device).

Performing Volume Calibration

Make sure the flow sensor (including the adapter) is attached tightly to the calibration syringe. Verify that the piston of the syringe is completely inserted



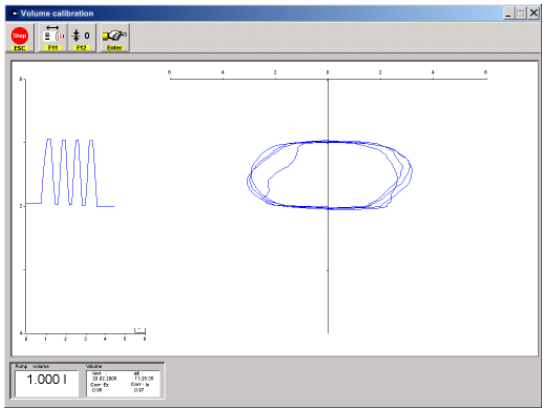
The syringe volume (1.000L in this case) can be changed by selecting the [F4] icon.

To start recording , press 

and begin to pump steadily.

A well defined and constant volume of air is pumped through the flow sensor.

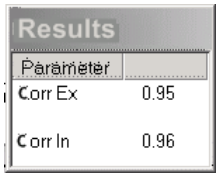
To ensure an identical volume is provided in every stroke, the syringe's piston has to be pushed in and pulled out as far as possible.



The recording of the volume/time curve is displayed.

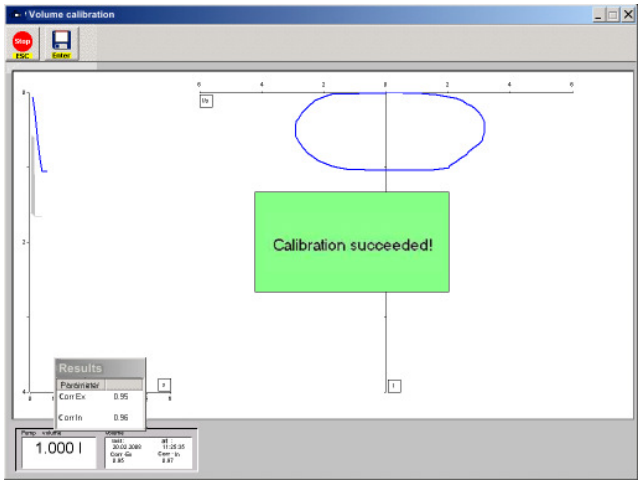
After about 5 to 10 pump strokes, select 

to end the calibration and begin the analysis. Results of the analysis are displayed in the following window. The calibration factors for each flow direction are stated.



Important : The condition for a valid calibration is an absolutely precise calibration syringe. nSpire Health is able to provide appropriate devices.

If the flow sensor works properly, a green field will be displayed in the calibration window.



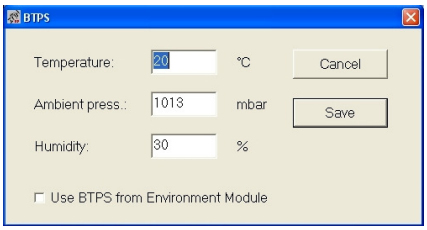
Select 

to complete the calibration and save the calibration parameters.

If the difference between Corr In and Corr Ex exceeds 6% or if either calibration factor deviates from 1.00 by more than 10%, the flow sensor should not be used. A note to replace the flow sensor will be displayed in a window. After replacement of the flow sensor, the calibration process must be repeated.

Note: The flow sensor that failed calibration should be carefully cleaned and the holes of the flow sensor should be checked to verify they are not blocked. After drying the flow sensor, perform a new calibration. If the calibration fails a second time, the flow sensor should not be used.

After saving the calibration results, some devices will still prompt you to enter the ambient conditions.



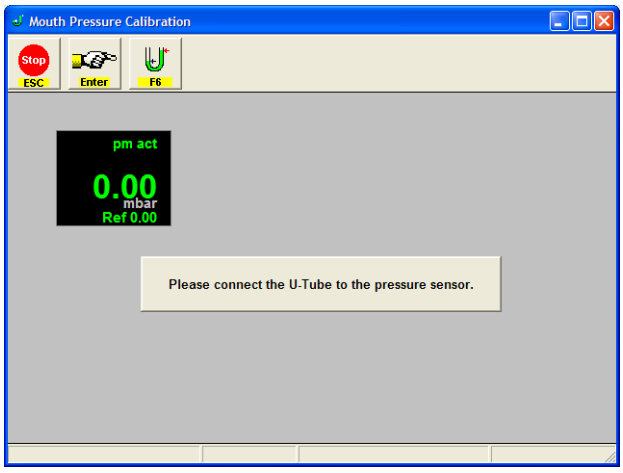
Please adjust them and save them by clicking on the “Save” button. If the “Cancel” button is selected, the existing values will be used

As mentioned before, the absolute pressure is needed here, not the pressure at sealevel. To help you to input the right values, ZAN offers you an additional so called 'environment module' which provides the necessary data by clicking the 'use BTPS' checkbox.

3.2 Mouth Pressure Calibration

Mouth pressure calibration is performed using the shutter. A pressure transducer is employed to measure pressures inside the flow sensor. The mouth pressure measurement is achieved directly and is therefore generally stable for a long time.

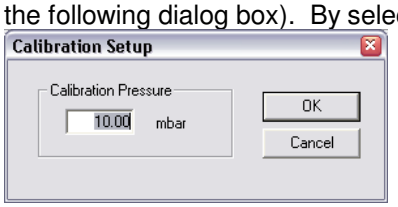
The accuracy of the mouth pressure transducer can be checked by using an appropriate pressure manometer (maximum ±50mbar) and through an access panel on the front of the device.

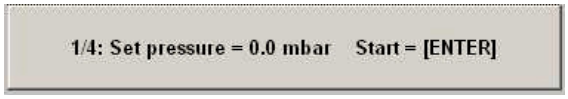


Note : Mouth pressure calibration should be performed during the measuring system inspection, which should be performed at least once a year.

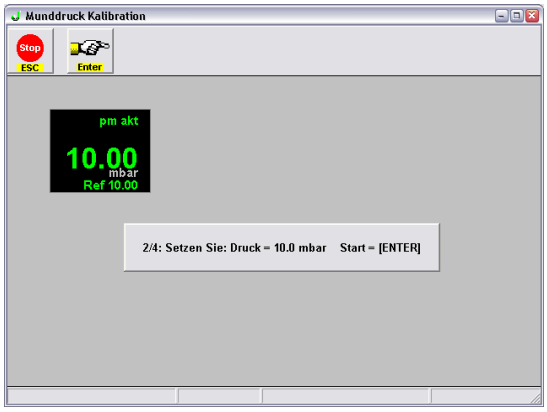
To calibrate the mouth pressure transducer, click on the mouth pressure symbol (resembling a U-tube manometer) in the calibration window.

Calibrations are performed by introducing an accurate 10 mbar pressure change to the transducer (see the following dialog box). By selecting [F6], different calibration values can be entered or used.

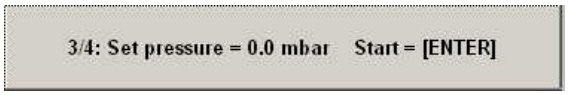




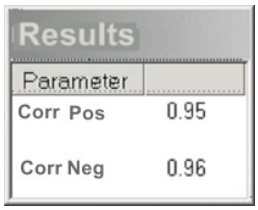
Follow the instructions on the screen. First, attach the pressure manometer tube to the mouth pressure connection, located next to the connection cable on the backside of the flow sensor. Next, select **[Enter]** and the following dialogue will be displayed:



Use a 5ml syringe and the manometer to produce the reference pressure.



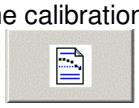
The results are displayed..

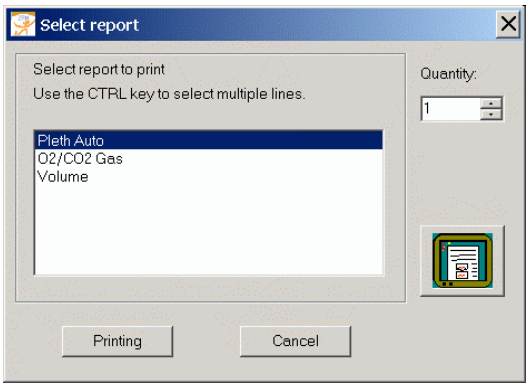


Select 

to save the calculated correction factors.

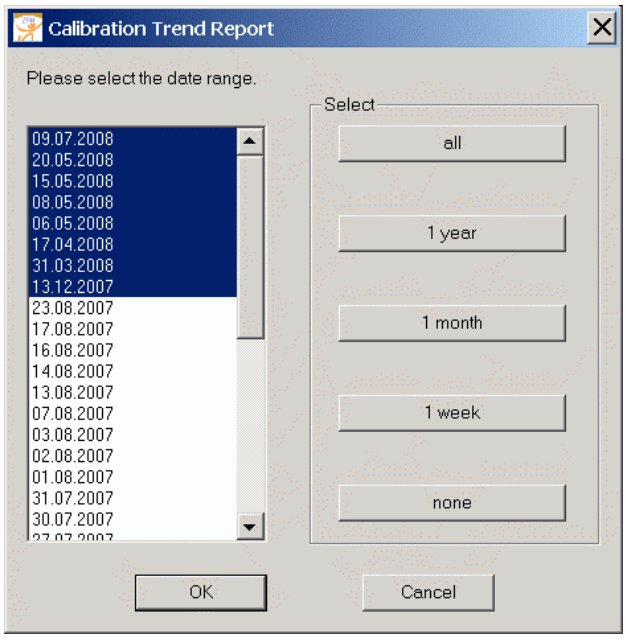
3.3 The Calibration Trend Reports

In order to control the quality of the calibrations, trend reports turned out to be very useful. To create a calibration trend report, press the  button in the calibration menu.



Select a particular report type from the list.

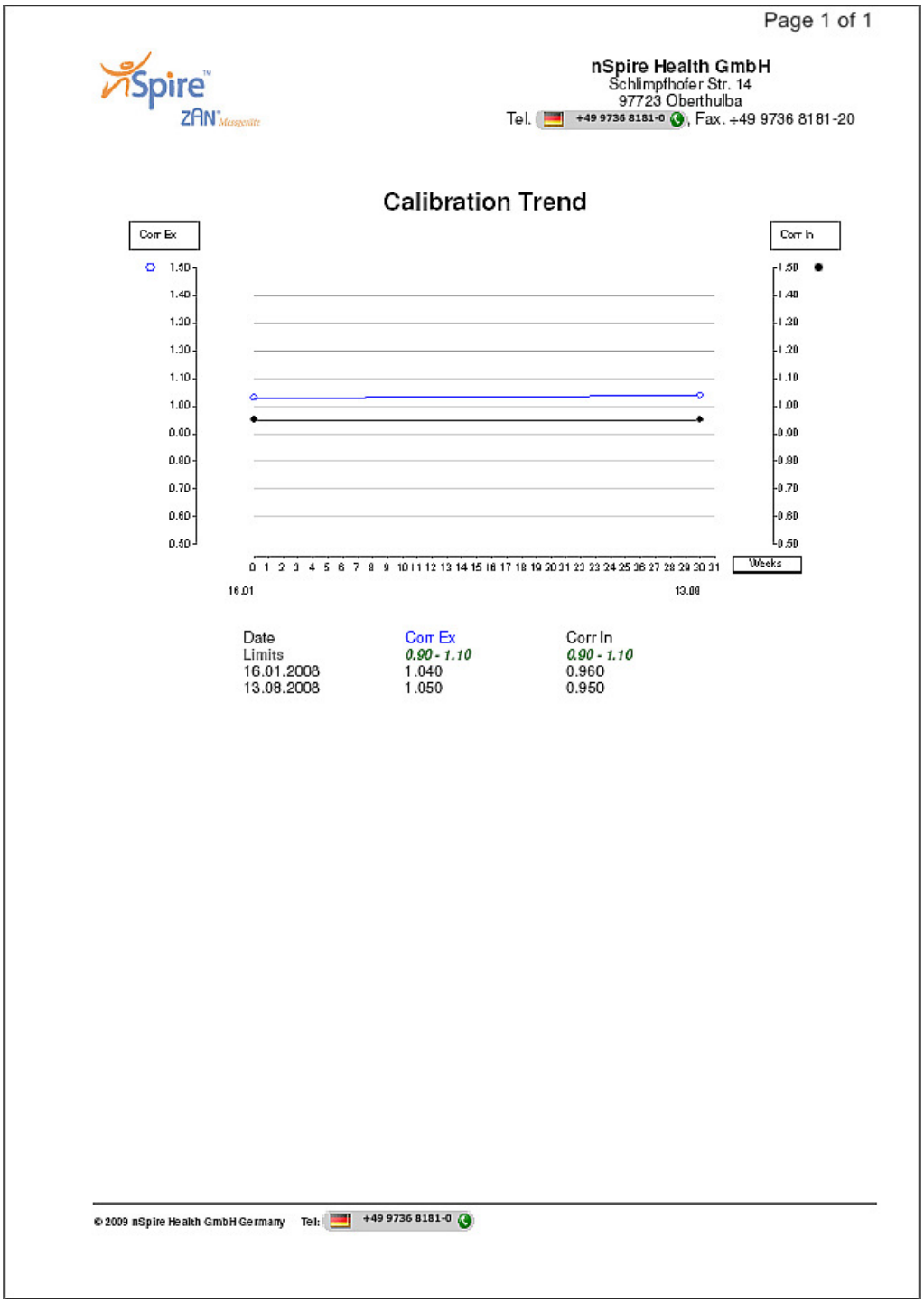
Selecting the preview button or the "printing" button leads to the date-range dialogue.



In the date – range dialogue select the period of time to be examined. Click on the desired date to select it. Select multiple dates by holding the 'control' key down during selection of dates. There is a list of shorthand buttons on the left side of the dialog for quickly select frequently used ranges. 'year', 'month' and 'week' select the current year, month or week. 'None' clears all selections.

[OK] starts the print out

After a few seconds, the print starts on your printer or, when preview was selected, the report is displayed on the screen.



Page 1 of 1

nSpire Health GmbH
Schlimpfhofer Str. 14
97723 Oberthulba
Tel. +49 9736 8181-0, Fax. +49 9736 8181-20

Calibration Trend

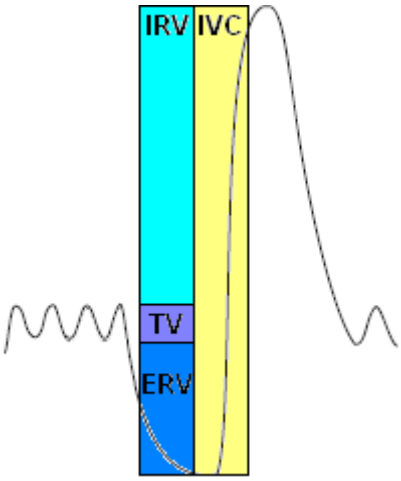
Date	Corr Ex	Corr In
Limits	*0.90 - 1.10*	*0.90 - 1.10*
16.01.2008	1.040	0.960
13.08.2008	1.050	0.950

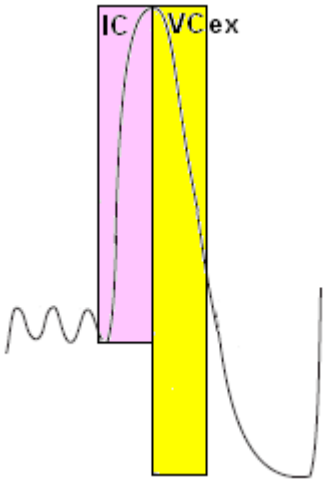
On closing this display, the programme returns to the main menu.

4 Measuring Procedures

4.1 SVC Measurement

SVC (Slow Vital Capacity) is a physiological test that measures how an individual inhales or exhales volumes of air as a function of time. The manoeuvres to measure the individual parameters are unforced, except at the point of reaching end expiration or end inspiration, where extra effort is required. The volumes that can be measured in spirometry consist of the following:





Abbreviation	Name	Definition
TV	Tidal Volume	The volume of air inhaled or exhaled during the respiratory cycle.
ERV	Expiratory Reserve Volume	The volume of air that can be maximally exhaled from a position of passive end-tidal expiration.
IRV	Inspiratory Reserve Volume	The volume of air inhaled from a position of passive end-tidal inspiration.
IC	Inspiratory Capacity	The volume of air inhaled from a position of passive end-tidal expiration.
VC	Inspiratory Vital Capacity	The maximal volume of air inhaled from the point of maximal exhalation.
VCex	Vital Capacity (expiratory)	The maximal volume of air exhaled from the point of maximal inhalation.

4.1.1 Measuring Separate Partial Volumes

The most important reference point of respiration is the Tidal Volume (Vt). At the end of tidal expiration, the retraction power of the thorax and the contraction power of the lungs are balanced.

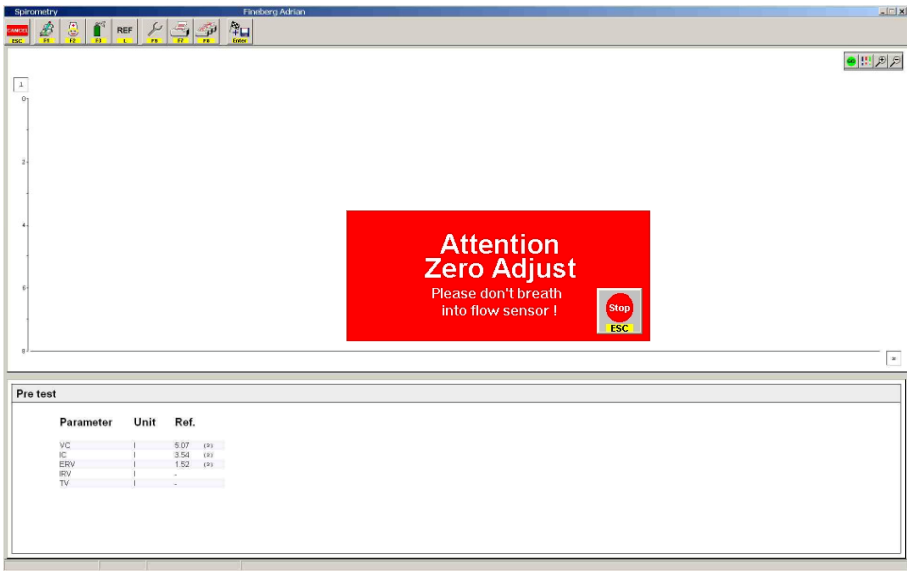
ERV is measured by having the patient exhale steadily and as deeply as possible. Some patients may take a small breath in before they exhale. This does not affect the results.

Once the patient has exhaled as deeply as possible, they should be encouraged to inhale maximally or as deeply as possible. This manoeuvre enables the calculation of the other spirometric parameters.

It is also possible to perform this measurement by getting the patient to inhale maximally from tidal breathing before exhaling as deeply as possible.

4.1.2 SVC Window

This window is displayed in the MEASURE mode after clicking on the spirometry symbol. After selecting the measurement, the following window is displayed:



Caution: During this measurement, the flow sensor will be zeroed, so it is important that there is no flow through the sensor. This process takes approximately 5 seconds.

4.1.2.1 Symbol Definitions

Select this icon or press the [ESC] key to stop the measurement and exit the programme.

Select this icon or press the [F1] key to display a dialogue box in which you can enter comments.

Select this icon or press the [L] key to select a reference value from another test for comparison.

Select this icon or press the [F2] key to define the user.

Select this icon or press the [F9] key to enter the test set up

Select this icon or press the [F3] key to select the medication.

Select this icon or press the [F7] key to print a single test result.

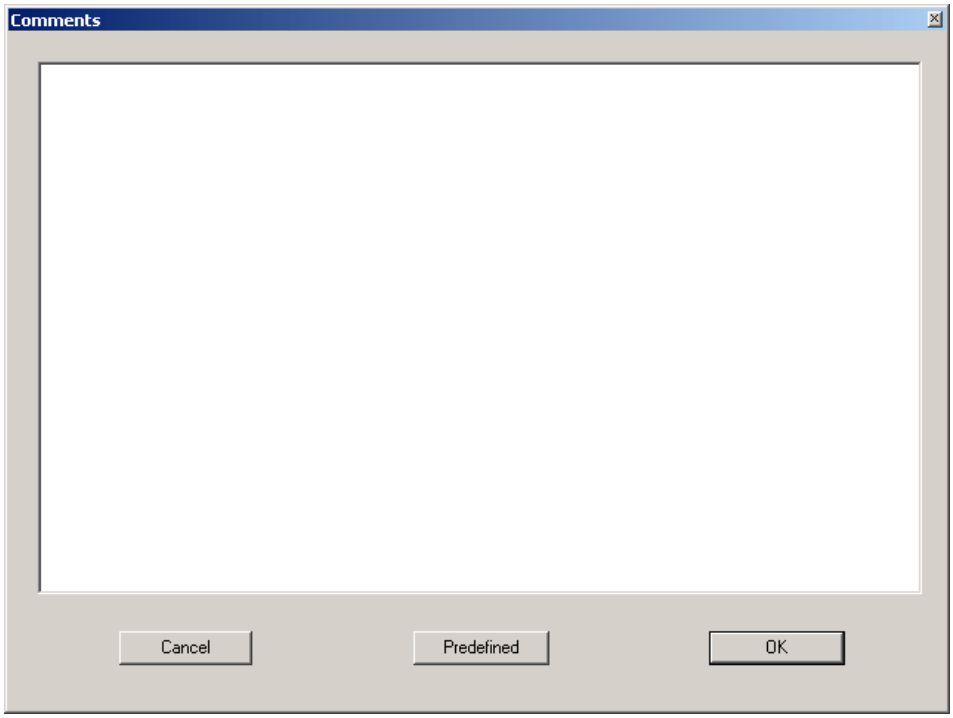
Select this icon or press the [F8] key to print out one or multiple templates

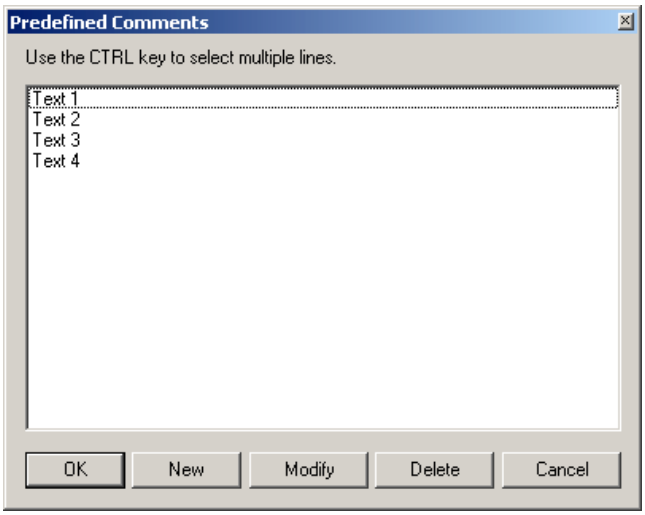
Select this icon or press the [F12] key to Check the results meet ERS/ATS 2005 Standards

Select this icon or press the [Enter] key to save the measurement and exit module.

4.1.2.2 Enter Comments

Selecting this icon or the [F1] key opens the comments dialogue box. Comments can be typed into the dialogue window and saved by pressing OK. By pressing the "Predefined" button, predefined comments can be inserted by using the second shown dialogue box . This dialogue box allows the user to create, modify and delete predefined comments. Each predefined comment consists of a full text and a short description, which is shown in the list box. Multiple predefined comments can be selected by pressing CTRL during selection.





4.1.2.2.1 Define User

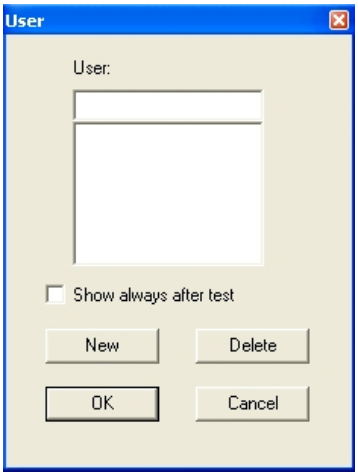
Selecting this icon or the [F2] key enters the test operator's name. This is saved with the patient record. The user entered is applied to all tests that are carried out on the active patient. The user has to be defined for every new patient.

User name field

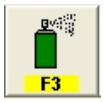
Pre-entered user name selection box

Display dialogue automatically at the end of the test

Clear User name field and insert new user name



4.1.2.2.2 Select Medication



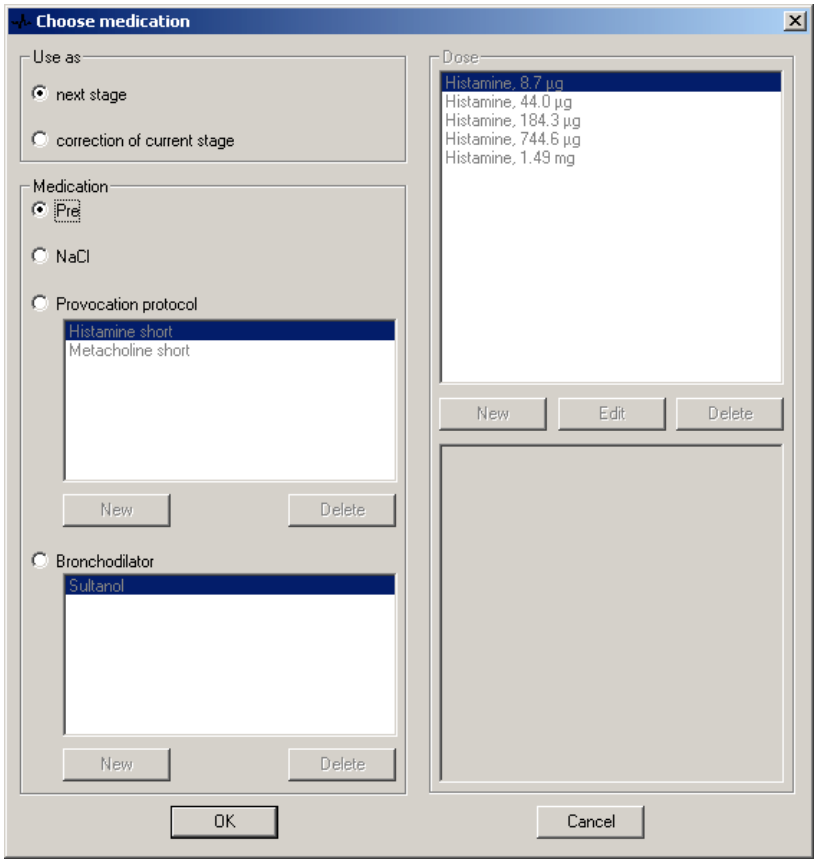
Selecting this icon or pressing the [F3] key selects the medication for the next stage.

The medication and dose given to the patient can be selected from the current medications entered into the system. The user has the choice to correct the medication for the current stage or to define the medication of the next stage.

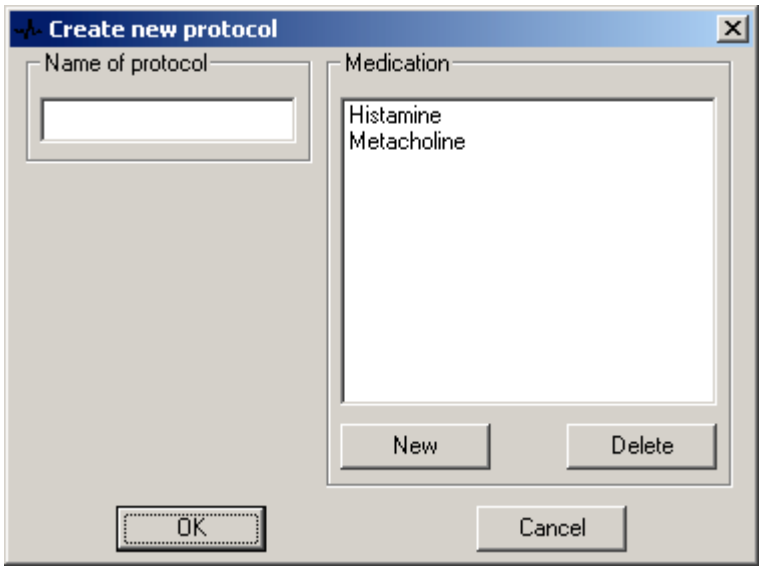
On the left hand side of the window, the user is able to select the test stage. This can either be a Pre-stage without medication, a NaCl-stage, a dose of a provocation protocol or a bronchodilator (Post-Stage).

For a dose, the user needs to first select a protocol from the list. It is also possible to create a new protocol (see below). As soon as a protocol is chosen, the possible doses of this protocol are shown in the list box on the right hand side. (If the dialogue box is opened during a provocation protocol, the protocol in use and the next dose are selected automatically). Again, the user has a choice to create, edit (see below) or delete doses. On the bottom right hand side of the window, the user is shown how to do the provocation to get to the selected dose. This includes concentration, nebuliser and count of nebulisations. For the count of nebulisations, the computer calculates the difference between the target dose and the dose currently in the lung (0 if not cumulative).

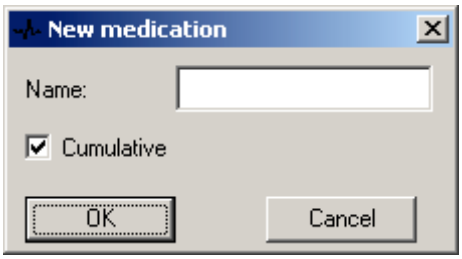
For bronchodilators, it is possible to either select none of the medications in the list box or one of those listed. Bronchodilators can be created or deleted.



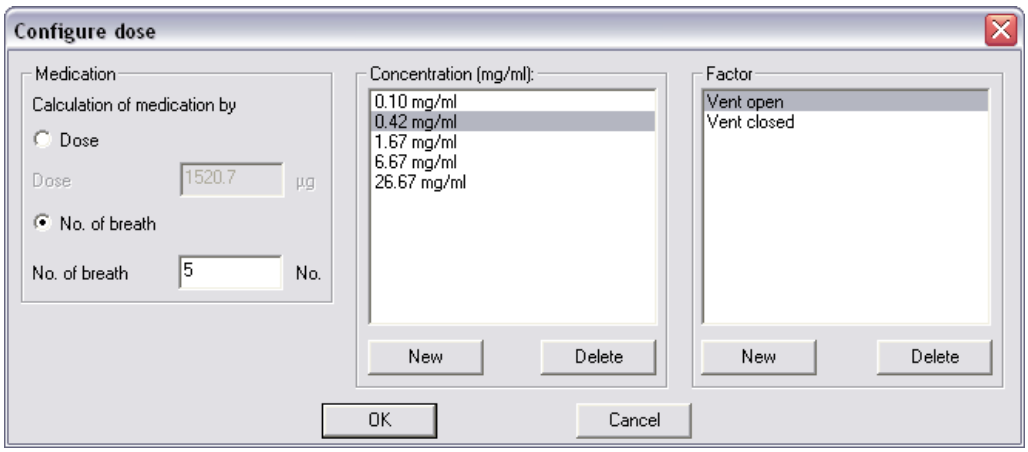
With the dialogue box shown below, new provocation protocols can be created. The protocol needs to be given a unique name. The medication that is used in the protocol needs to be chosen from the list. Medications can be deleted as long as they are not being used by other protocols. New medications can also be created.



When creating a new medication, the dialogue box below appears. It allows the user to enter the name of the medication as well as if the medication is cumulative.



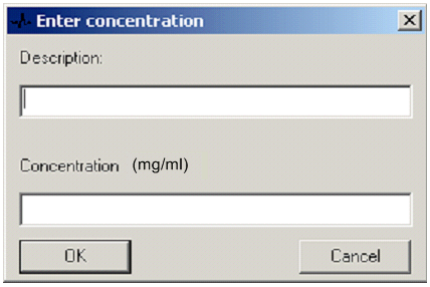
The dialogue box shown allows the user to create or edit a dose. It has an entry field for the dose (read only when editing an existing dose) as well as a list box for the concentration and the factor to be used. Again, elements can be added to or deleted from the list boxes (as long as they are not being used by another protocol).



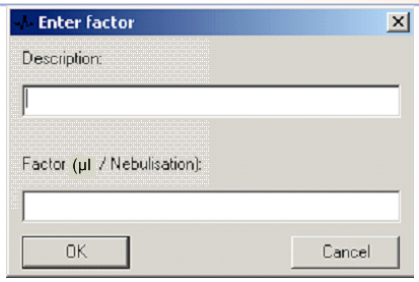
Since the ATS '5 breath protocol' requires 5 nebulizations, an additional way to define the protocol exists calculating the dose by the number of breath's. Simply check the 'No. Of breath' radio button and enter the desired count of breath to calculate the doses.

To enter a new concentration, use the dialogue box shown below. The description is the text that is shown in the list box and allows the physician to determine the correct dose concentration. The concentration is entered in mg/ml.

To enter a new concentration, use the dialogue box shown below. The description is the text that is shown in the list box and allows the physician to determine the correct dose concentration. The concentration is entered in mg/ml.



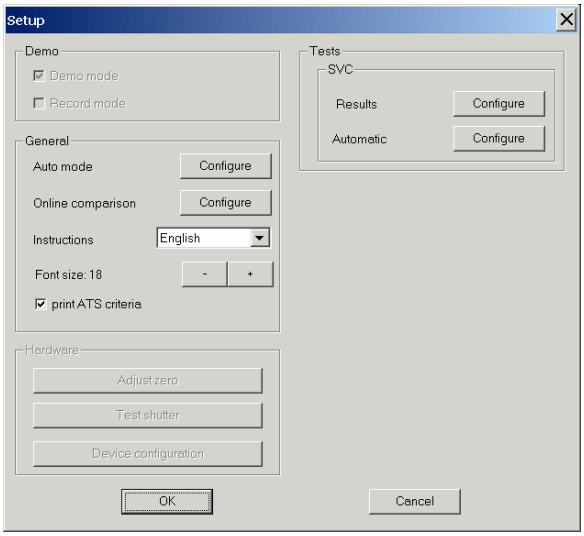
To enter the factor of the nebuliser, use the dialogue box below. The dialogue box allows the entry of a description (for instance the name of the nebuliser) as well as the volume (in µl) that is nebulised per nebulisation.



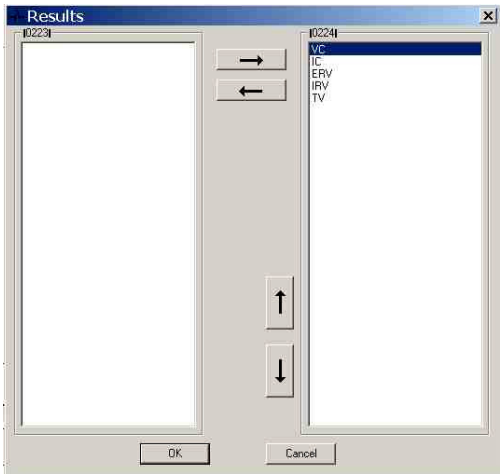
4.1.2.3 System Set-up

Selecting this icon or the [F9] key enables the configuration of the spirometry programme and the selection of system components.

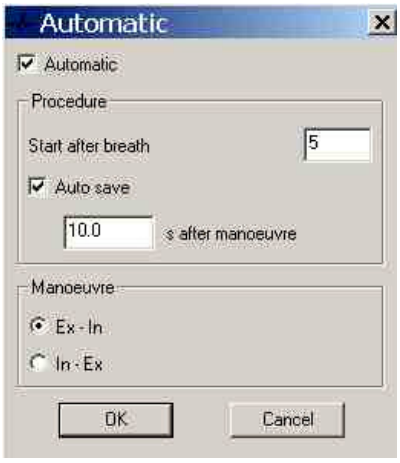
The Set-up screen has three active sections: Test Set-up, General Settings and Hardware Set-up.



Test Set-up allows you to select the results shown after the test and to set up automatic saving of the results. When you click on the configure keys you get the following screen graphics.

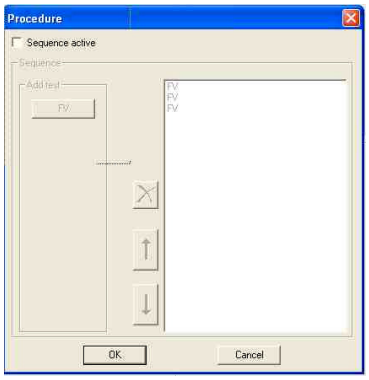


This screen allows you to set up the number of baseline breaths before performing the test.



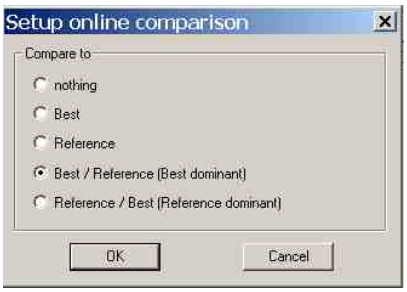
It allows the choice of an inspired or expired breath as the first breath of the test, and offers you the opportunity to enter the elapse time, after which the test is automatically stored.

The General mode allows you to set up an automatic sequence, for example the sequence shown below allows you to set up 3 consecutive FVC tests.



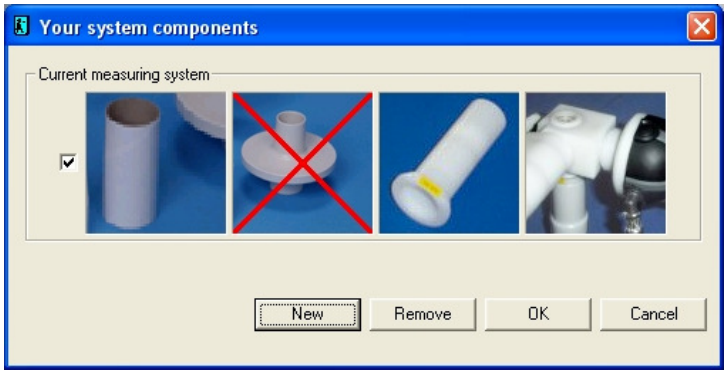
The general setting gives online comparison settings, language settings and auto mode settings

The online comparison settings allow you to compare to best test, to reference, or to nothing. This corresponds to the test that is shown in red when performing a test.



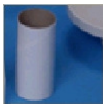
The current language options include English, German, French and Spanish. This language setting only affects the instruction texts during measurement. This feature allows test instructions to be seen in alternative languages for patients who need instructions in a different language.

The Hardware Set-up allows you to reset the shutter, zero the flow sensor and set up the component for the test as seen below.



Symbol Definitions

By double clicking with the left mouse button it is possible to enter one of the option menus and select the appropriate component.



Select from mouthpiece options.

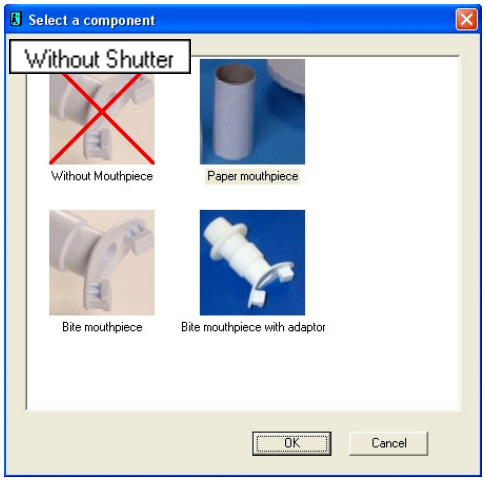
Select from filter options.

Select from Flow sensor options.

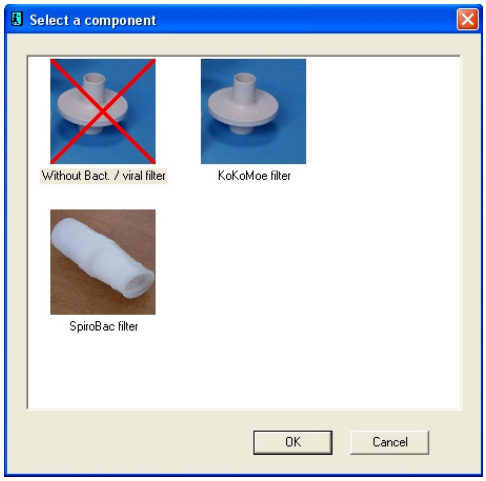
Select from shutter options.

To view the current configuration, hold the cursor over the appropriate option field.

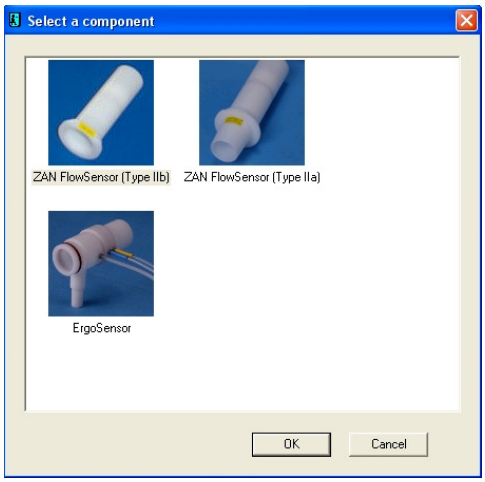
Default mouthpiece options



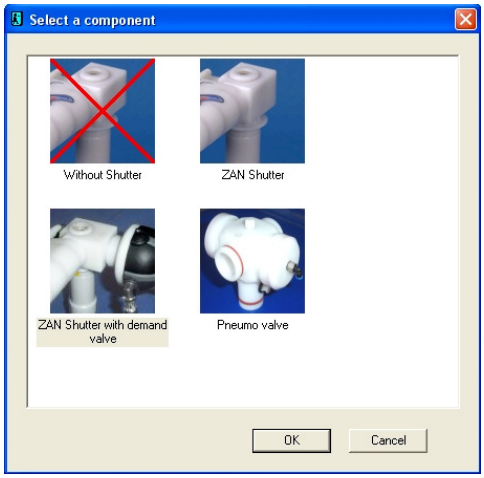
Default filter options



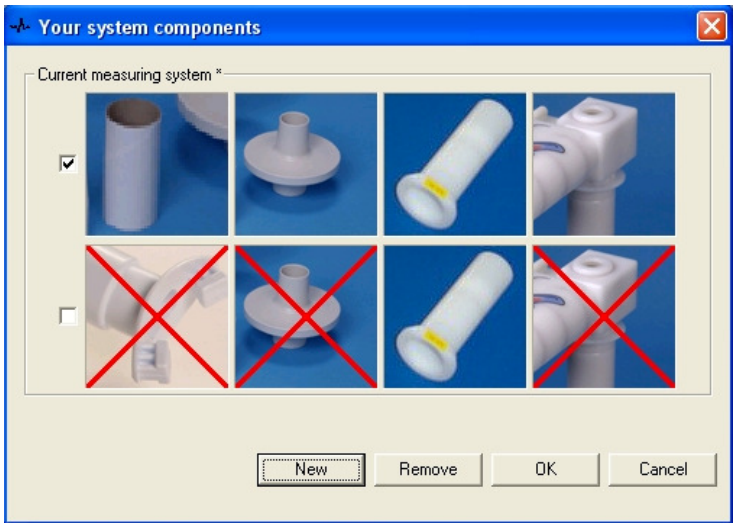
Default flow sensor options



Default shutter options



Save multiple configurations for easy selection by pressing the [New] button.



4.1.3 Performing SVC Testing

Select this icon (located at the right hand side of the screen) to start the measurement.

4.1.4 Symbol Definition

Select this icon or press the [ESC] key to end the test without saving.

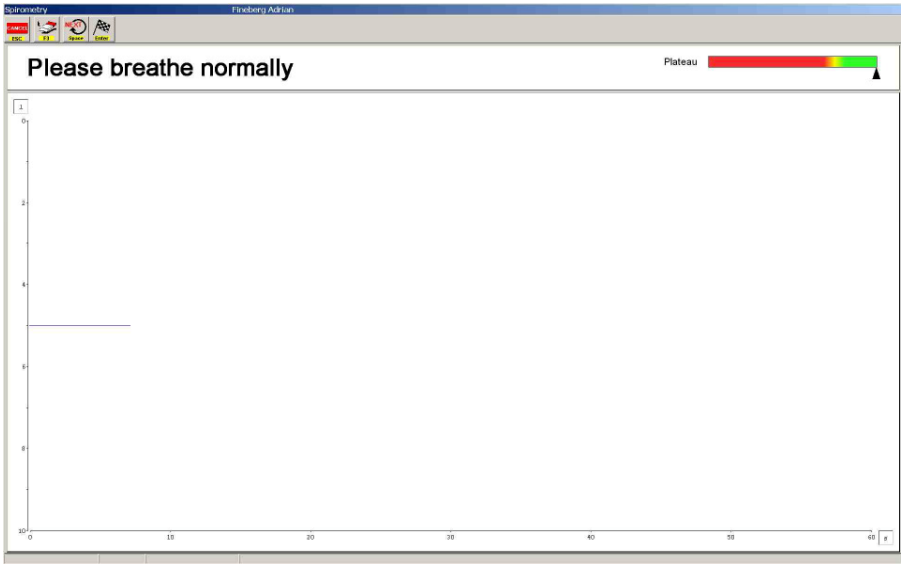
Select this icon or press the [Enter] key to save the measurement and exit.

Select this icon or press the [space] key to save the measurement and start a new measurement.

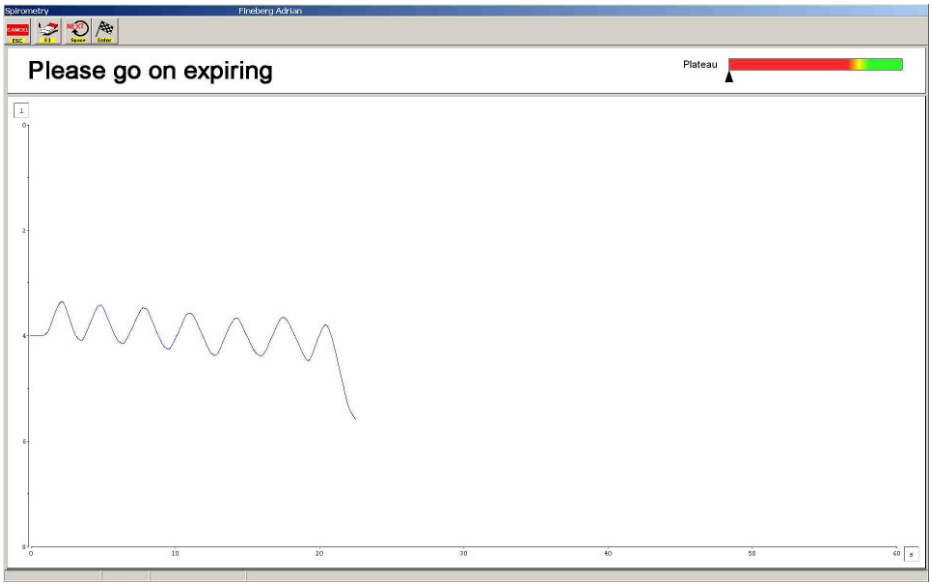
The volume trace is displayed on the graph as a blue line and scrolls from left to right. The patient should use a nose clip and form a tight seal around the mouthpiece with his or her lips. The patient should breathe normally through the mouthpiece. The following example is an Ex-In manoeuvre.

These have the same structure, but with inhalation instead of exhalation.

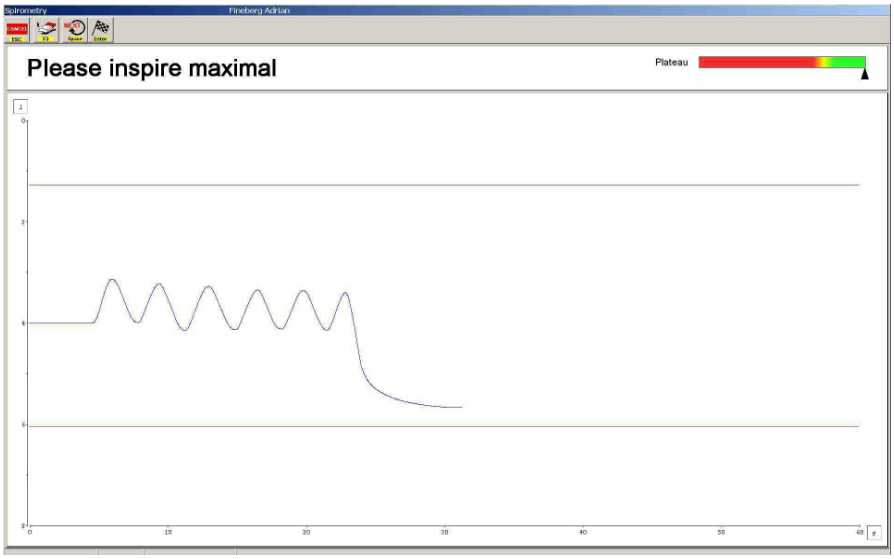
If the trace is unsatisfactory, the measurement can be re-started by pressing the [F3] key. This deletes the results and continues the measurement.



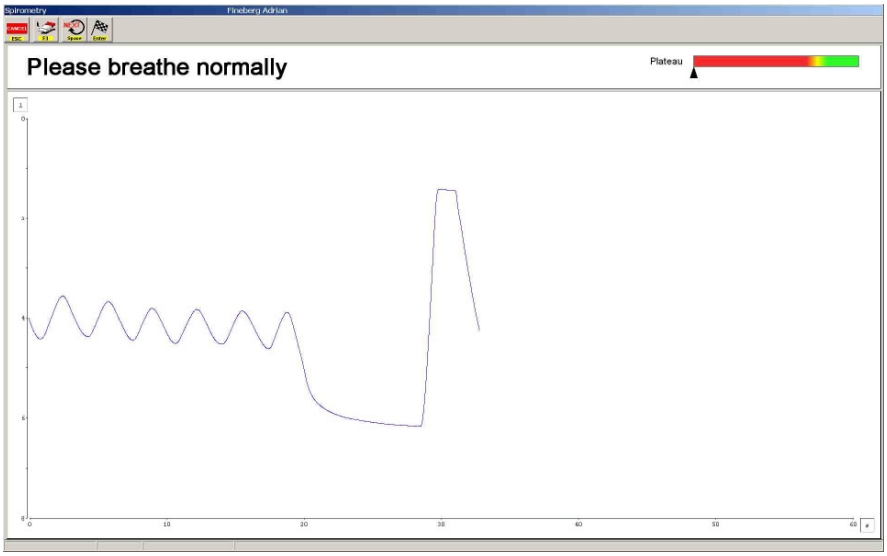
To determine the tidal volume, the patient should breathe normally through the mouthpiece. If the automatic mode is selected in the set-up (after the predetermined number of breaths) the computer instructs you to expire maximally. The patient should be encouraged to exhale slowly for as long as possible.



When the lungs are completely empty, the computer will instruct you to perform a deep steady inhalation. During this procedure the plateau slide bar gives an excellent indication of whether or not the patient is close to the end of their breath.



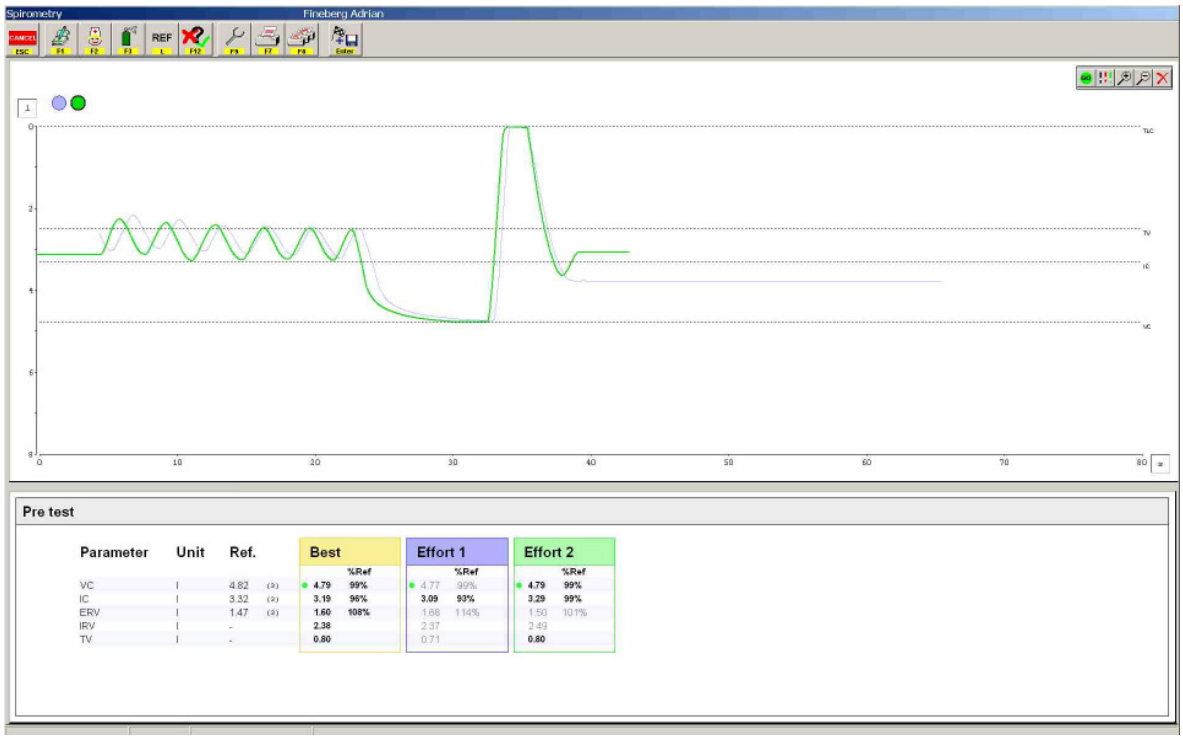
At the end of the inhalation, the patient can return to normal tidal breathing.



If a test is available for online comparison, two lines will show the corresponding vital capacity. The first manoeuvre that touches or crosses a line moves both lines, so that the curve will not cross this line. By having this visual help during the test, the user can easily determine whether the effort is reproducible with respect to the online comparison.

Additional VC manoeuvres can be performed when the patient is rested and ready. Once sufficient manoeuvres have been made, press 

to end the test and display the results. The following screen will be displayed at the end of the test.



The efforts are colour coded and the tabular data is shown at the bottom of the screen. You can choose to view the graphics as a volume/time trace or as a bar graph by clicking the bar graph symbol on the right hand side of the screen. To zoom in and out, use the magnifying glass icons

The computer automatically selects the best effort to be reported for this stage. This is shown by the highlighted coloured dot . You can change the computer decision by left-clicking on a different coloured dot.

ATS/ERS have provided criteria for the acceptance of the test. The computer will automatically determine whether the criteria for acceptance are met. If an effort is not acceptable, this is shown by a red cross over the corresponding coloured dot. To remove the effort from the selection process right-click on the coloured dot.

The fulfilment of ATS-criteria is also visualised by the result table. Green and red dots show for each parameter that is defined by ATS, whether the criteria were met or not. This includes the criteria for acceptance as well as those for reproducibility (only shown when more than one effort performed).

The result window also has a column called “Best”. This column shows the results that are reported for this stage. The results of the single efforts that are taken into account for the creation of the “Best” are plotted in bold. The value that is reported is either from the selected effort, the maximum of all accepted efforts, the mean of all accepted efforts or recalculated. The standard methods are according to ATS.

4.1.5 SVC Guidelines

In many cases, the patient is nervous before the measurement, resulting in erratic tidal breathing. The patient's respiration should be corrected by verbal encouragement to give a more stable baseline for the rest of the measurement.

To ensure accurate results, the patient should be encouraged to exhale and inhale completely. This is demonstrated by a plateau at the end of each part of the manoeuvre.

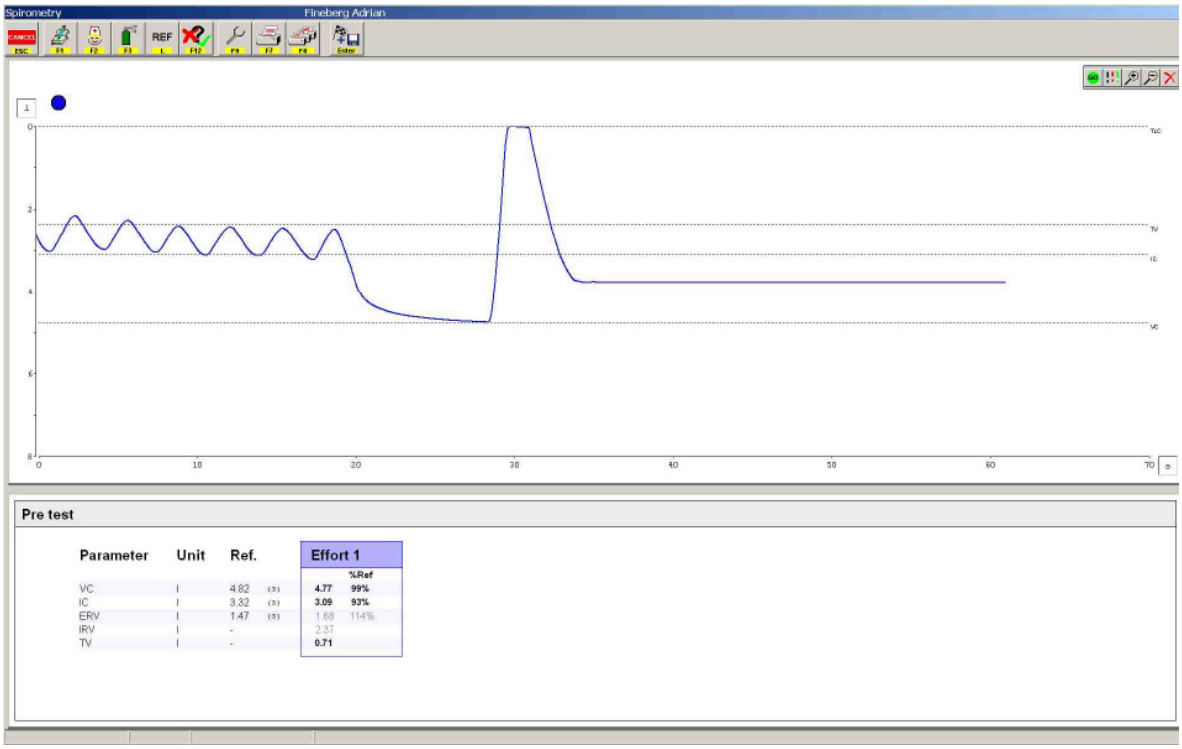
If there is an air leak from the patient at the mouthpiece or the patient comes off the mouthpiece, the measurement should be repeated to achieve correct calculations of the partial volumes.

4.1.6 Co operation

To ensure accurate and reproducible results, the patient should be encouraged throughout the measurement. It is recommended that the test be repeated until three acceptable manoeuvres have been obtained. Optimum co operation will result in reproducible results.

4.1.6.1 Adjusting Lung Volume Sub-Divisions Manually

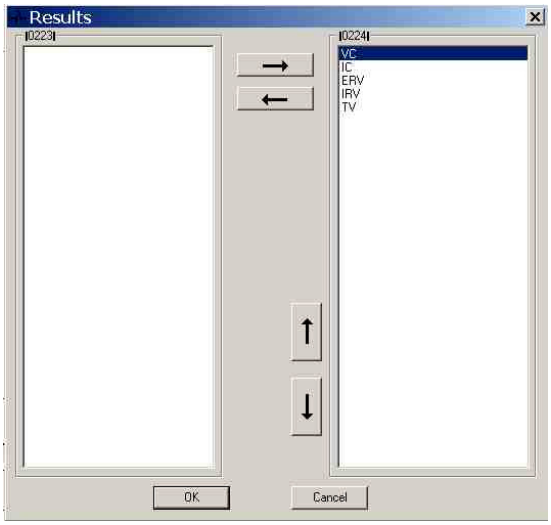
The position of the lung volume sub-divisions can be changed and the values re-calculated by selecting one of the lines with the mouse and holding down the left mouse button. To illustrate the line was selected with the mouse; it is shown as a thicker green line.



4.1.7 Parameter Selection

To alter the parameters displayed in the results table, open the set-up function using the 

button.



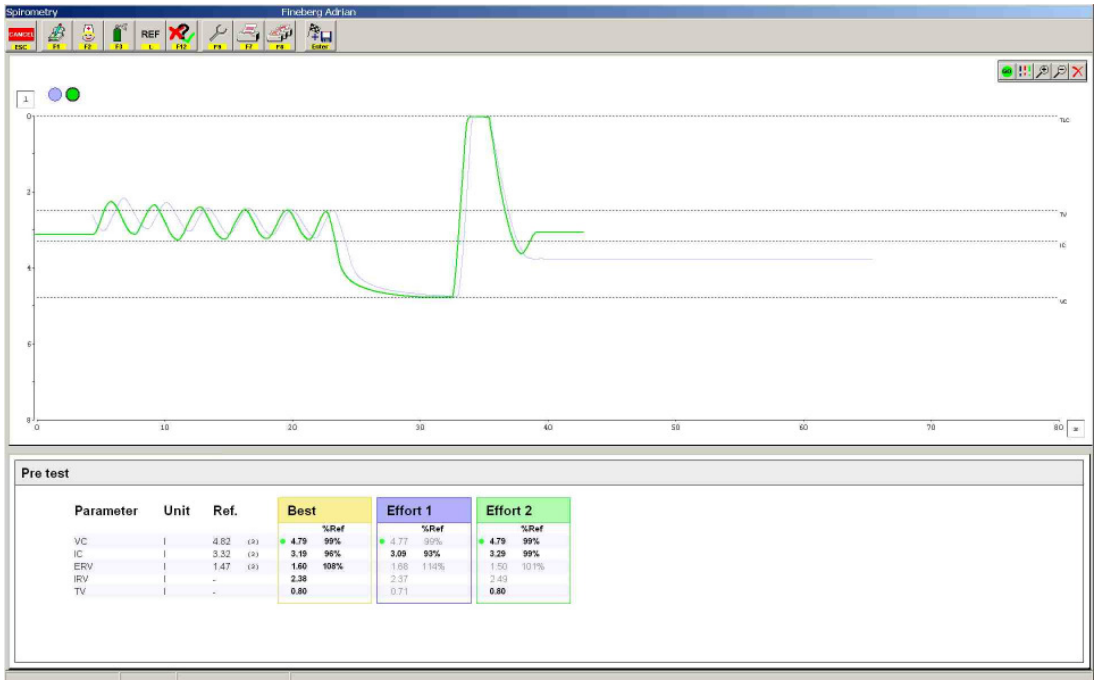
From the “All Measurements” list, you can select the parameters you want to view in the results table. These parameters will be inserted into the “Selected Measurements” list.

4.1.7.1 Symbol Definition

-->	Moves the selected parameter into the “Selected Measurements” list (right window).
<--	Removes the selected parameter from the “Selected Measurements” list (right window).
▲ ▼	Moves the parameter up or down in the “Selected Measurements” list (right window).

4.1.8 Viewing Measurements

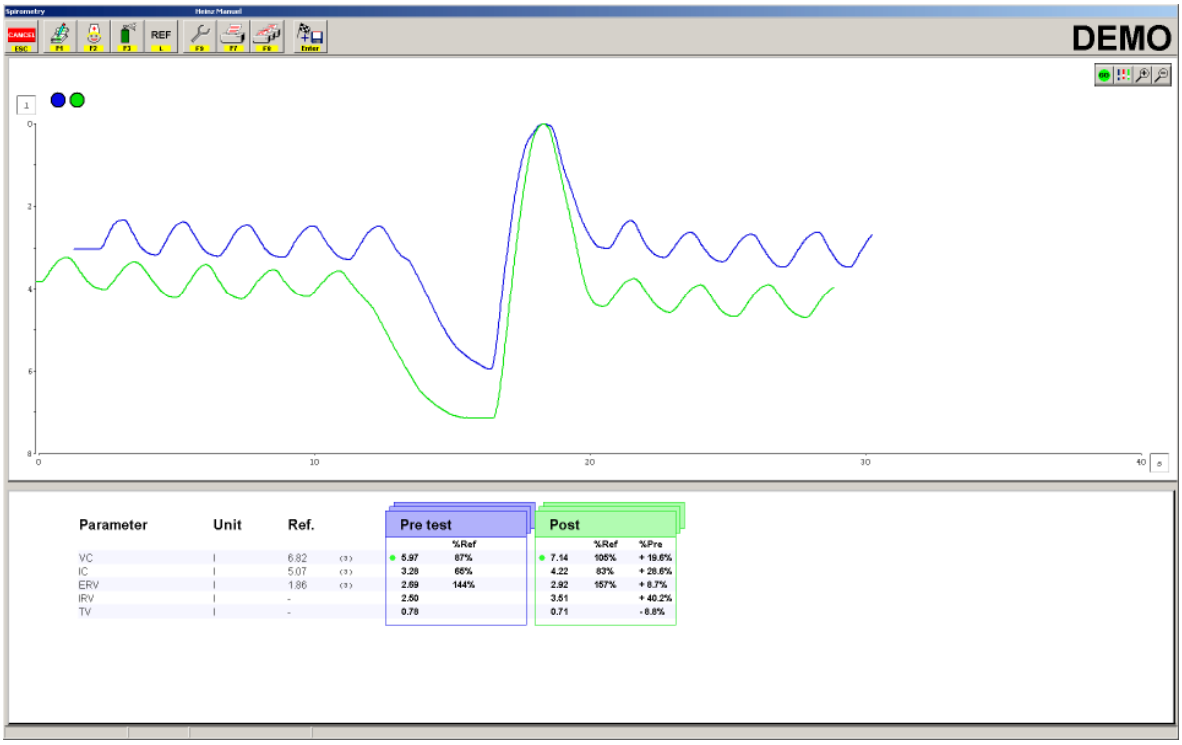
In the “View” mode, all measurements (or only selected ones) can be viewed.



The software has two different views in which it can show the test results. The first is the Effort View. This view shows all efforts of one stage and allows the user to correct efforts by the use of tangents to determine the effort that represents the stage. The second view is the Slot View. This view shows the “Best” effort of each stage. This viewing mode allows Pre/Post comparisons as well as trending for provocation tests.

If in the Effort View screen, the name “Effort View” will be shown in the grey header of the result window. To move to the Slot View, left-click within the result window.

To change from Slot View (see picture below) to Effort View, left click within the result window on the column of the stage you want to see the efforts from. While in Effort View the coloured dots are used to select the best curve, set the acceptance of an effort, or highlight multiple curves for better visual comparison.



4.1.8.1 Comparison to references

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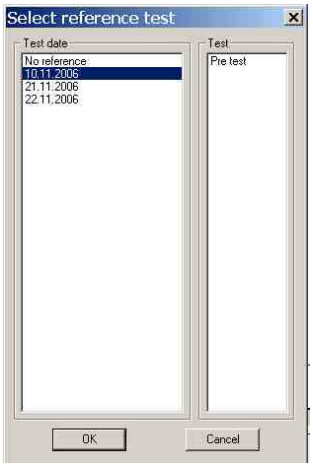
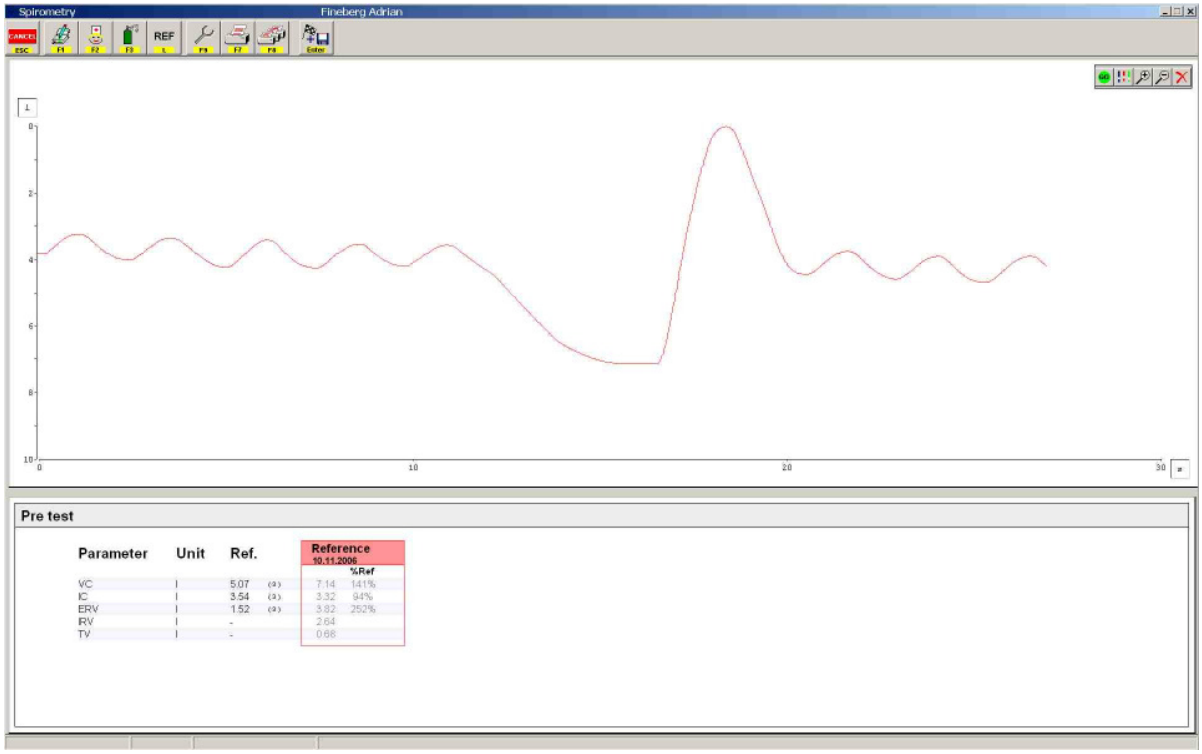


You can select a previous test to compare the SVC measurement to, even if it was performed on a previous visit. Click the 

icon and the reference list will come up. Select the date and type of test and click ok.

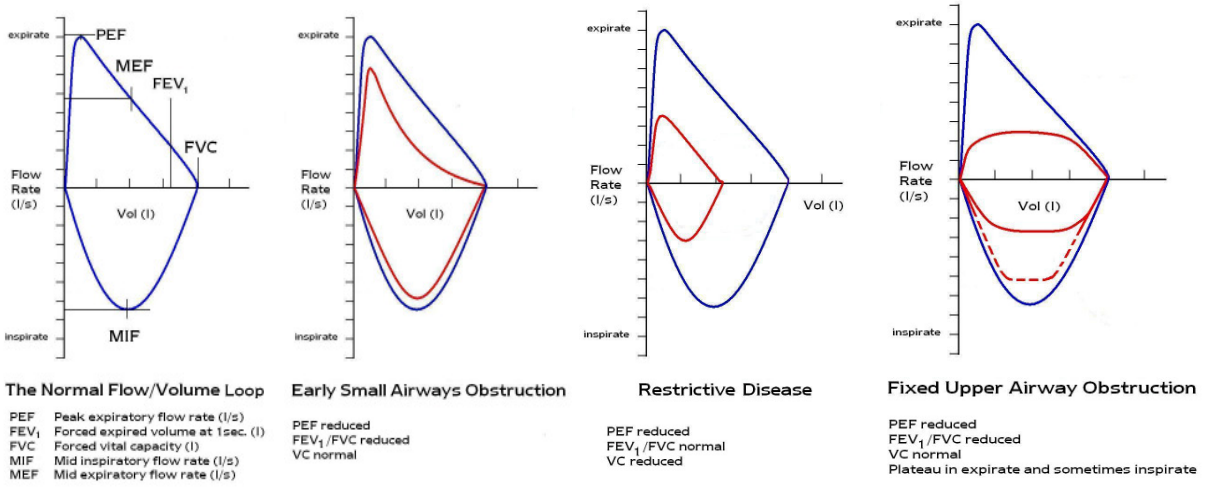
You will then see the comparison of current data to the reference selected.



4.2 Flow/Volume Measurement

4.2.1 Definition Of A Flow/Volume Measurement

The Flow/Volume loop is the recording of the flow rate plotted against the volume. The flow/volume loop shows the lung's reaction during maximum flow speed. According to the constitution of the lung tissue, the expiratory flow is more or less strongly limited. Typical loops will occur according to specific lung constitutions.

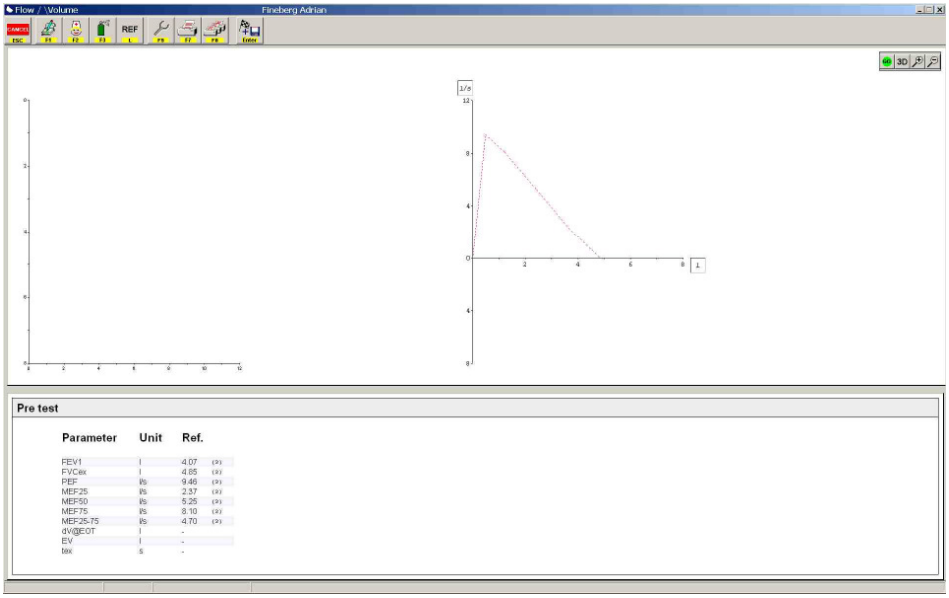


4.2.2 Important Measurement Parameters

Short name	Name	Meaning
FVC	Forced vital capacity.	Maximum expiratory volume with maximum flow speed.
FEV1	Forced expiratory volume within the 1st second of exhalation.	Volume that can be forcefully exhaled within the first second.
PEF	Peak expiratory flow.	Maximum flow speed during exhalation.
MEF 75	Flow at 75% of expiratory volume.	Flow speed after 25% of exhalation.
MEF 50	Flow at 50% of expiratory volume.	Flow speed after 50% of exhalation.
MEF 25	Flow at 25% of expiratory flow.	Flow speed after 75% of exhalation.
FEV1/FVC	Ratio between FEV1 and FVC.	Obstruction parameter.
AEX	Area underneath the expiratory curve.	Equivalent to FEV1.
PIF	Peak inspiratory flow.	Peak flow during inhalation.
MI[F5]0	Flow at 50% of inspiratory volume.	Flow speed after 50% of inhalation.

4.2.3 Flow/Volume Screen before Measurement

This window is displayed in the MEASURE mode after clicking on the Flow/Volume symbol.



4.2.4 Symbol Definitions

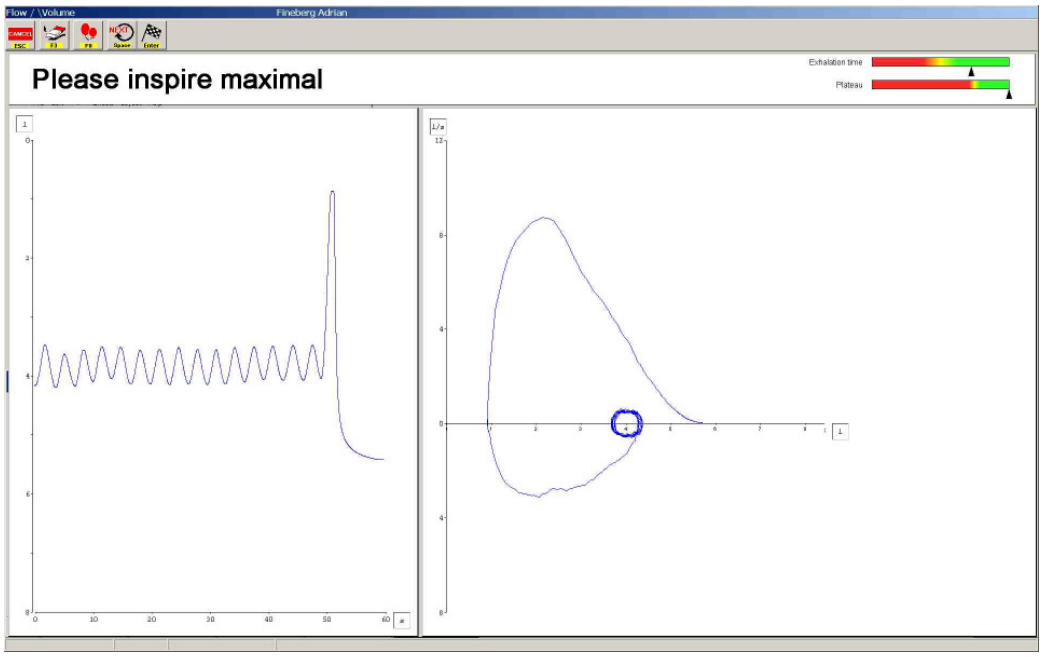
	Select this icon or press the [ESC] key to stop the measurement and exit the programme.		Select this icon or press the [F1] key to display a dialogue box to enter comments.
	Select this icon or press the [L] key to select a reference value from another test for comparison.		Select this icon or press the [F2] key to define the user.
	Select this icon or press the [F9] key to enter the test set-up		Select this icon or press the [F3] key to select the medication.
	Select this icon or press the [F7] key to print a single test result.		Select this icon or press the [F8] key to print out one or more templates.
	Select this icon or press the [F12] key to check that results meet ERS/ATS 2005 Standards		Select this icon or press the [Enter] key to save the measurement and exit module.
	Click the go icon to start the test		The 3D icon switches to view graphic in 3D the magnifying glass icons zoom in and out
			The 2D icon switches graphics into a 2D view
	The button V/t switches graphics to the Volume/Time graph (button only available, if not F/V and V/t on the screen at the same time)		The button F/V switches graphics to the Flow/Volume graph (button only available, if not F/V and V/t on the screen at the same time)

4.2.5 Performing a Flow/Volume Measurement

On the screen the recording of the volume/time curve displays in the left part of the window. The flow/volume loop (on the right) displays when respiration starts.

Caution: It is important that the patient uses a nose clip and forms a tight seal around the mouthpiece.

The patient should perform several tidal breath's before executing a the FVC manoeuvre. Using the delete key F3, the recording can be re-started and the screen can be cleared.



4.2.6 Symbol Definitions

Select this icon or press the [ESC] key to stop the recording without saving any data.

Select this icon or press the [Enter] key to stop recording the measurement.

Select this icon or press the [F3] key to delete previous recordings.

Select this icon or press the [space] key to save and perform another effort.

Select this icon or press the [F8] key to switch on incentive graphics.

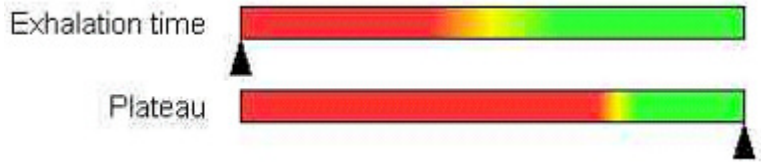
Every click on this icon will change the screen to a new incentive graph.

4.2.7 FV Measurement Guidelines

A flow/volume measurement with meaningful results demands the optimum co-operation of the patient. It is important that the patient inhales and exhales the complete volume of his or her lungs with maximum flow speed.

You have to distinguish between an inspiratory and an expiratory F/V curve. To measure the inspiratory curve, the patient has to slowly exhale the complete volume of his or her lungs in order to inhale as fast and as deeply as possible afterwards. In order to measure the expiratory flow, the patient has to exhale as fast and as deeply as possible after maximum inhalation.

To guarantee a complete exhalation, it is recommended to exhale for at least 6 seconds. During the measurement, a time bar will be displayed in the upper right of the screen. It starts to increase with each exhalation and changes colour from red to green after 6 seconds. When this occurs, the patient should inhale again. Also in the right hand side of the screen, is the plateau graphic which is an indication of flow nearing zero. This gives information to the technician on the quality of the manoeuvre performed by the patient.



4.2.8 Co-operation

To judge the patient's co-operation, the maximum exhalation should be repeated 3 times. It is important that the patient exhales as fast and as deeply as possible. With optimum co-operation, all curves will be positioned closely on top of each other and have a nearly identical form.

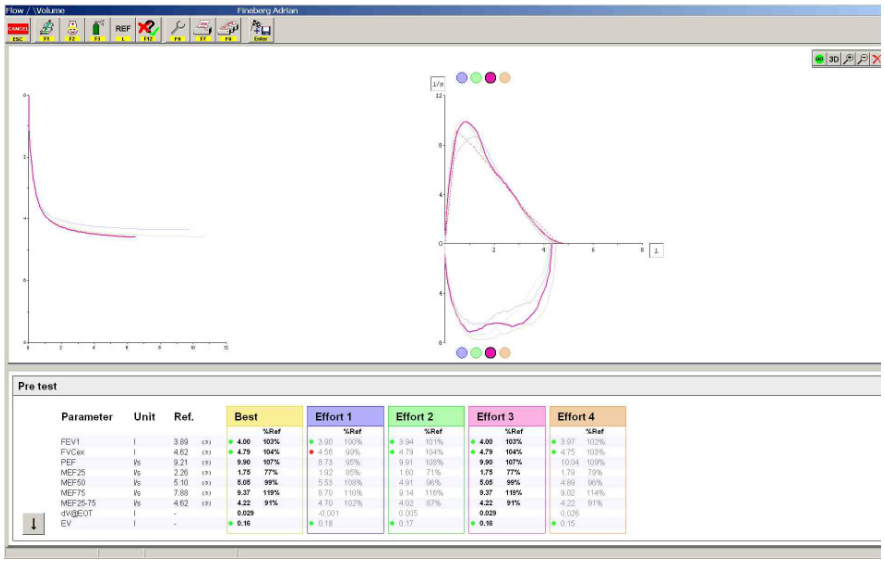
The curve's form will be pointed if the patient's co-operation was at an optimum. See picture below.

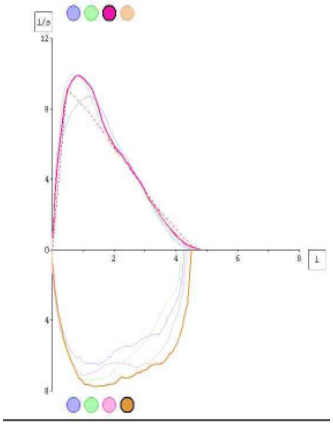
To exhale the whole volume, the patient must exhale for at least 6 seconds. The measurement curve must slowly merge into the base line.

To finish the measurement and display the results, press the 

icon

4.2.9 Flow/Volume Screen after Measurement and result edit





The four efforts are colour coded and the computer selects the best result. In this example, effort 3 is highlighted. You can mix and match the flow volume inspired and expired according to the ERS /ATS 2005 guidelines. Simply click on the coloured circle you wish to see for the final report (for both the top and bottom of the graphic). This example shows effort 3 for the expired loop combined with effort 4 for the inspired loop.

According to ATS there are criteria for the acceptance of the test. The computer will automatically determine, whether the criteria for acceptance are met. If an effort is not acceptable, this is shown by a red cross over the corresponding coloured dot. In order to remove a loop from the selection process you simply right click on the related coloured dot.

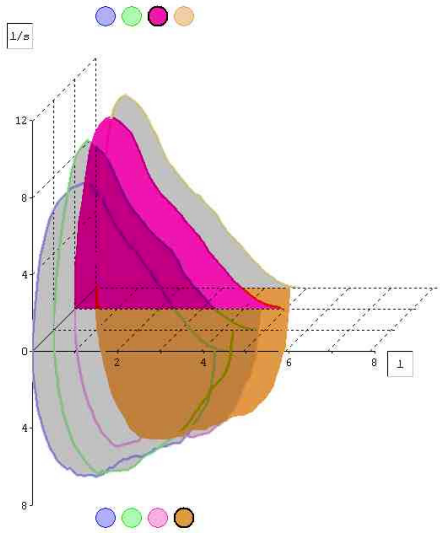
The fulfilment of ATS criteria is also visualised by the result table. Green and red dots show for each parameter that is defined by ATS and whether the criteria were met or not. This includes the criteria for acceptance as well as those for reproducibility (only shown when more than one effort performed).

The result window has a column called “Best”. This column shows the results that are reported for this stage. The results of the single efforts that are taken into account for the creation of the “Best” are plotted in bold. The value that is reported is either from the selected effort, the maximum of all accepted efforts, the mean of all accepted efforts or recalculated. The “Best” efforts are determined using ATS/ERS standards.

4.2.10 Different views of graphics

You can view the flow volume loops in the conventional 2 dimensional view or the newly available 3 dimensional view. The 3D view gives the added value of depth when looking at a number of loops together. To change the view, click on the 3D icon. 

You will get the following display for flow volume loops:



To return to the conventional view click the 2D icon  in the top right hand side of the screen

4.2.11 Quality guidelines

Select this icon or press the [F12] key to see if efforts conform to quality standards

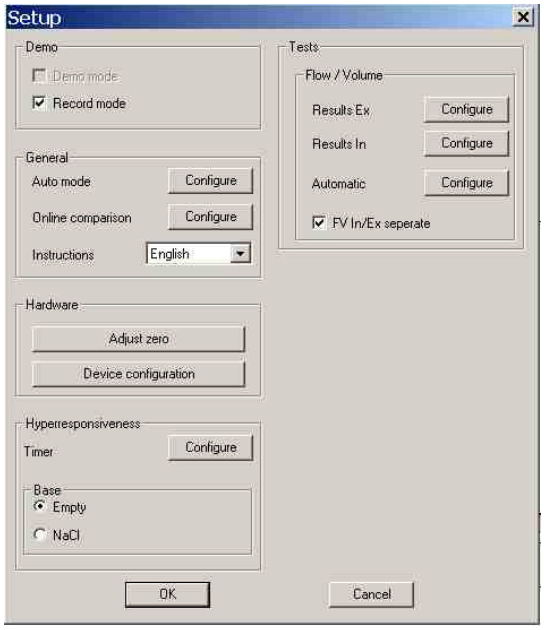
4.2.12 Set-up

By clicking on the 

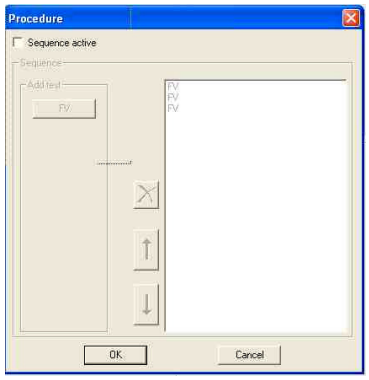
icon, you enter the test Set-up Menu

There are five sections of the Set-up menu: Demo Set-up, General Set-up, Hardware Set-up, Test Set-up and Hyper-Responsiveness Set-up.

The Demo Set-up mode is for sales purpose only, and should not be connected to the computer.

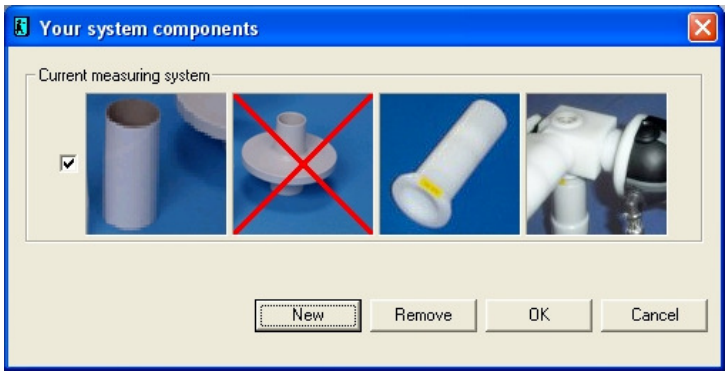


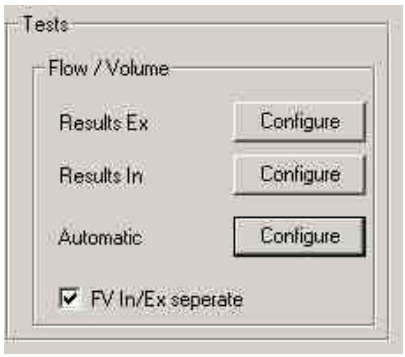
The General Set-up mode allows you to set up an automatic sequence, for example, if you always want to perform 3 FVC tests in a row, you can simply set up the sequence as shown below



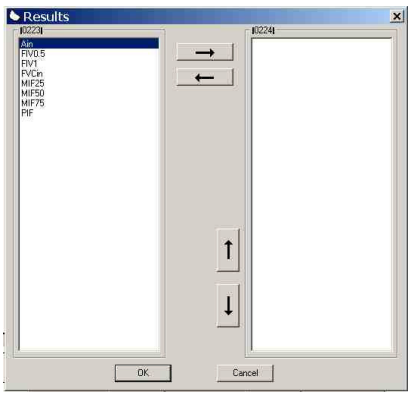
The “Set-up online comparison” dialogue allows you to configure result comparisons. Please see the dialogue box below for comparison options.

The hardware configuration allows you to reset the zeroing point of the flow sensor and configure the set-up of the device from a filter/mouthpiece perspective.

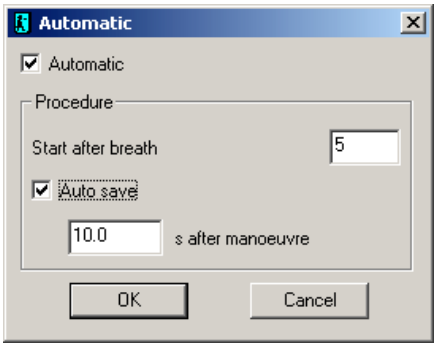




This allows you to set the parameters you want to see after the test is performed from both the expired and inspired results, and the order of the results displayed on the screen.



You can set the Automatic option, which allows you to automatically save the results of each test. In this way you can concentrate on the patient instead of having to push the enter key to save the trace at the end of the test



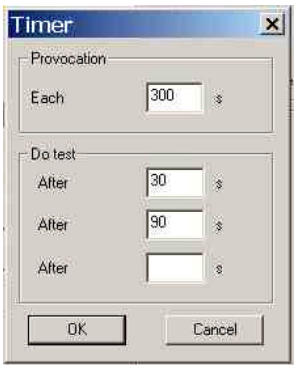
Finally, the 

tick box allows you to remove the ability to split the inspired and expired portion of the loop.

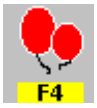
Under the Hyper-Responsive set-up you can configure the timer for the bronchial challenge program.

The timer is helpful for the user to do the provocations and after a defined time period, keep the cumulative effect of the medication. According to ATS/ERS, provocations should be performed every 5 minutes.

The test timers allow the defining of up to three time points, after the provocation, that the efforts should be performed. The ATS/ERS recommends that these efforts be performed at 30 and 90 seconds (respectively).

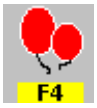


4.2.13 Animation Programme

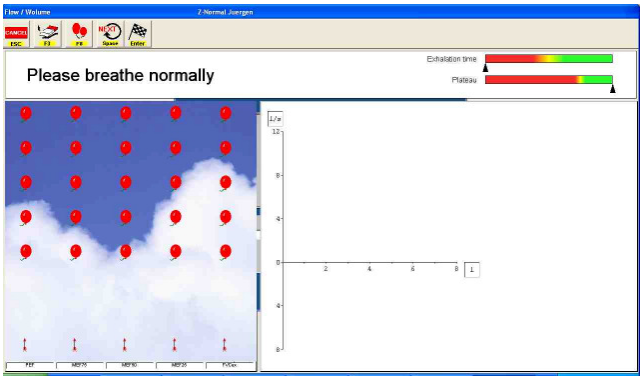
Select this icon 

or [F8] to display the animation programme. With each click, the animation selection changes.

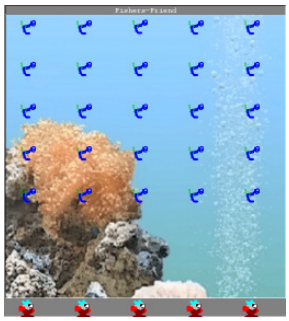
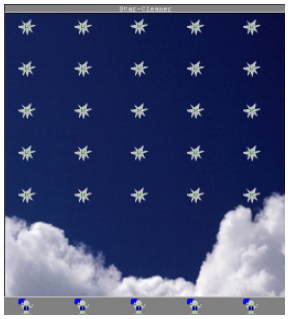
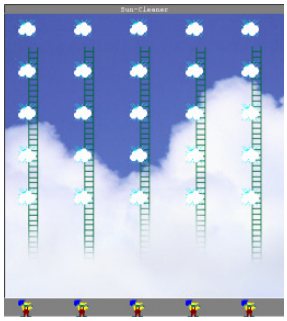
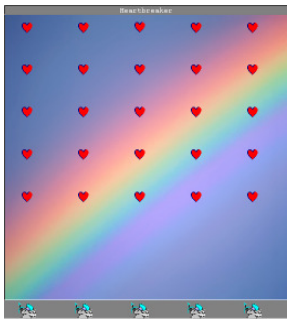
The animation programmes are meant to motivate patients, especially children, to help perform a maximum effort (for example, to make all the balloons burst).

Note: With each click on the 

icon , the animation selection changes.



Additional animation selections follow:

There are various motives.. Select the motive which your patient likes best.

To finish the measurement and display the results, press the 

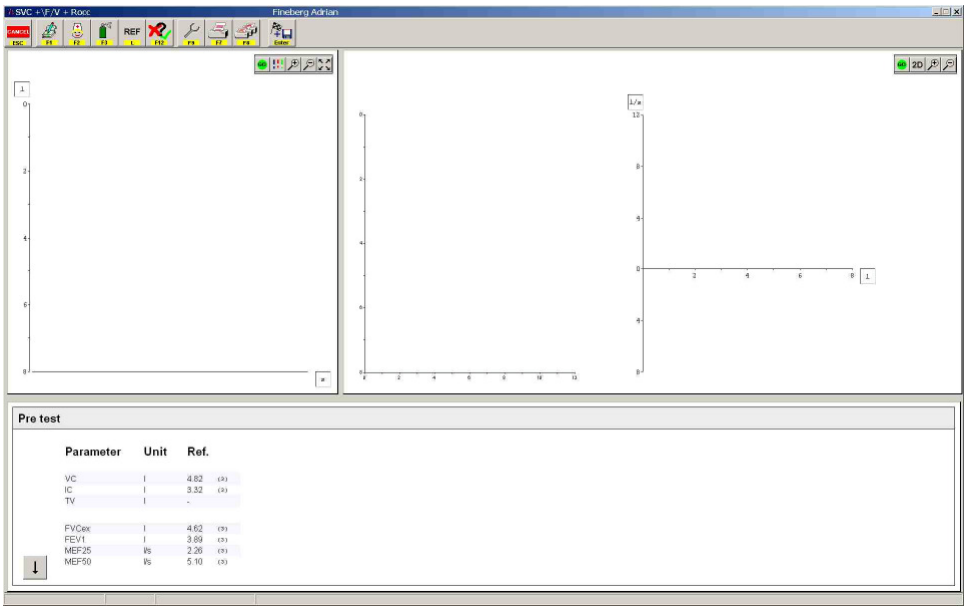
icon

4.3 Combined SVC and F/V Measurement

4.3.1 Combined SVC and F/V Measurement Window before Measurement

Selecting the icon 

in the MEASURE mode enables the measurement of SVC as well as F/V measurement with one single procedure.



4.3.1.1 Symbol Definitions

Select this icon or press the [ESC] key to stop the measurement and exit the programme.

Select this icon or press the [F1] key to display a dialogue box to enter comments.

Select this icon or press the [L] key to select a reference value from another test for comparison.

Select this icon or press the [F2] key to define the user.

Select this icon or press the [F9] key to enter the test set-up

Select this icon or press the [F3] key to select the medication.

Select this icon or press the [F7] key to print a single test result.

Select this icon or press the [F8] key to print one or more templates.

Select this icon or press the [F12] key to check that results meet ERS/ATS 2005 Standards

Select this icon or press the [Enter] key to save the measurement and exit the module.

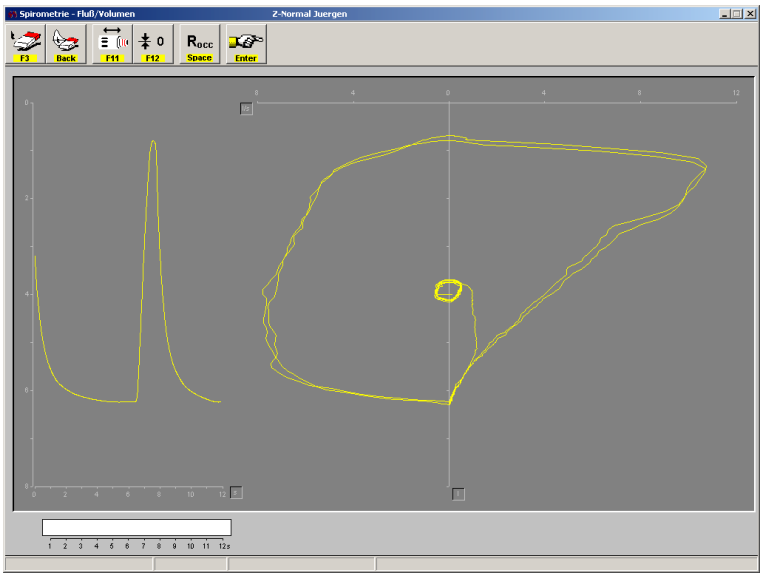
Click the go icon to start the test

The 3D icon switches to view graphic in 3D the magnifying glass icons zoom in and out

First the SVC Test is performed. Please refer to the SVC Chapter for detailed information.

Directly after the slow inspiration the forced expiration is performed. Please look for detailed information in the F/V chapter.

4.3.2 Airway Resistance Measurement (ROCC)



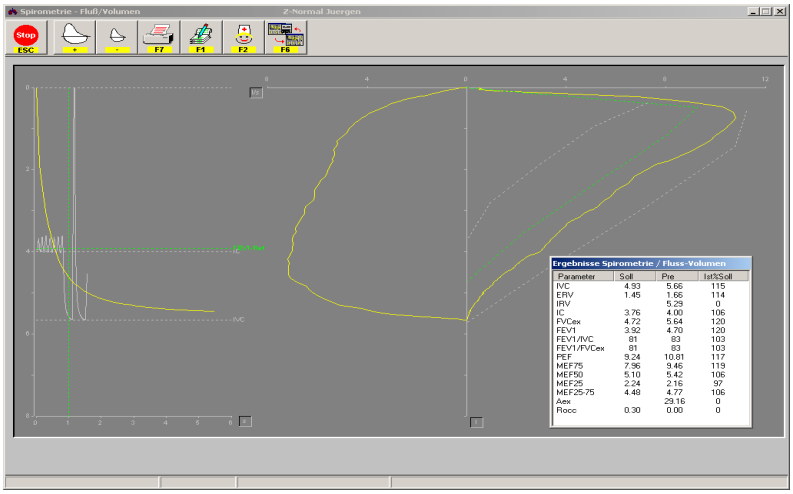
If your ZAN device is equipped with a valve (shutter), the respiratory flow can be interrupted during tidal breathing by pressing the space bar during a spirometry measurement.

If the pressure that was caused during the interruption is measured and divided by the flow that was caused after opening the valve, the flow resistance can be measured.

The last five measured interruptions will be analysed and displayed in the list of results.

If the valve does not close with the next exhalation after pressing the space bar, the patient was probably breathing too slowly. Either the breathing depth or the breathing rate must then be slightly increased.

4.3.3 Spirometry, Flow / Volume Screen after Measurement



4.3.3.1 Symbol Definitions

toggles the results table on and off.

saves the measurement.

4.3.3.2 Parameter Selection

By double clicking on the results table, a dialogue window is displayed with a selection of parameters. From the list of parameters, you can select the parameters you want to view in the results table. These parameters will then always be shown in the results table.

Look in the paragraph “Parameter Selection” in chapter “SVC” for detailed instructions.

The results and the measurement will be saved after pressing the 

key.

4.4 Measurement of the Maximum Voluntary Ventilation (MVV)

Maximum Voluntary Ventilation (MVV) is the maximum volume of air a subject can breathe over a specified period of time (12 seconds for normal subjects). This value is normally corrected to 1 minute and is expressed in l/min.

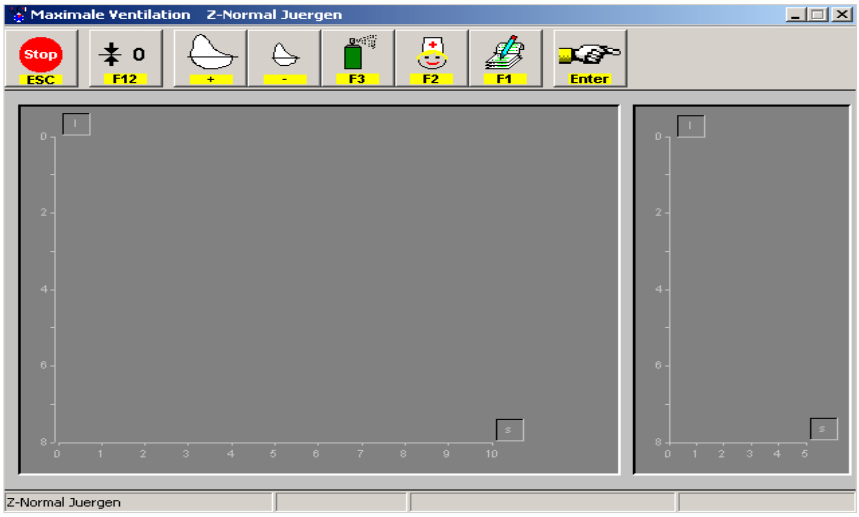
MVV may be useful in those conditions where ventilatory capacity may be impaired by mechanisms that are different to those affecting FEV_1. It can also be used to estimate maximum ventilation in cardio-pulmonary exercise testing.

MVV is measured by getting the patient to breathe in and out as rapidly and as deeply as possible for a specified time. It is similar to heavy panting. To obtain accurate results, only begin recording the measurement once the desired breathing pattern has been achieved.

4.4.1 How to perform the MVV Measurement

Selecting the icon 

in the MEASURE mode enables the measurement of MVV and will lead you to the measurement window



Symbol Definitions

Stop measurement and exit the programme

Select medication

Find Zero

Define User

Zoom in

Add Remarks

Zoom out

Start Measurement

4.4.2 Performing a MVV Measurement

Select this icon 

or press the [Enter] key to start the measurement.

On the screen the recording is displayed as a yellow line. The patient should place their lips around the mouthpiece, forming a tight seal, and breathe normally.

The patient should be instructed to begin breathing as rapidly and as deeply as possible. The recommended frequency is 30/minute.

Start measurement by selecting the 

icon again.

Note: It is important that the patient continues to breathe maximally throughout the recording phase. The measurement should use this kind of 'running start' to ensure optimum results.

The patient has to breathe maximally for 12 seconds.

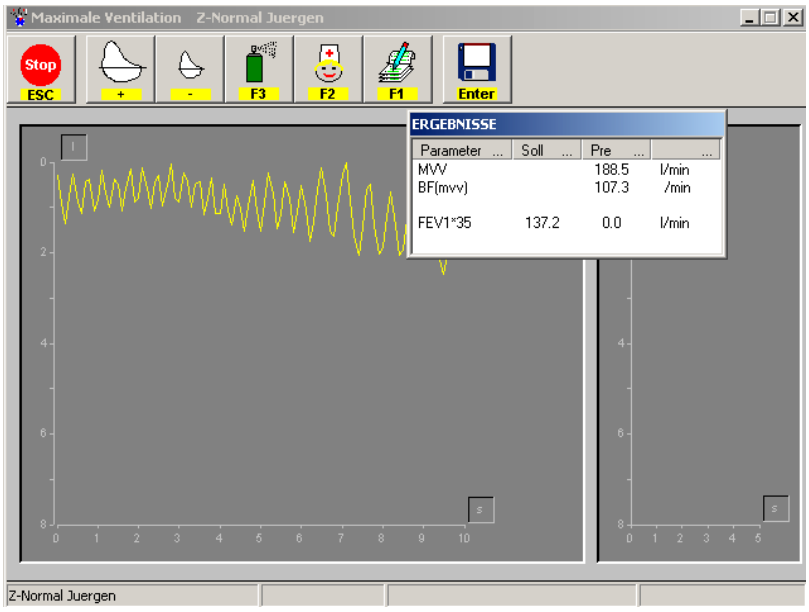
If the patient is unable to continue for the whole 12 seconds, it is possible to stop the measurement by selecting this icon 

at any time and calculate their results from the data that has been recorded up to that point.

The maximum minute-volume will be defined by extrapolation of the volume during the real measured time. After 12 seconds the measurement will finish automatically.

Select this icon 

or press the [Enter] key to save the measurement and exit.



4.4.3 MVV Measurement Guidelines

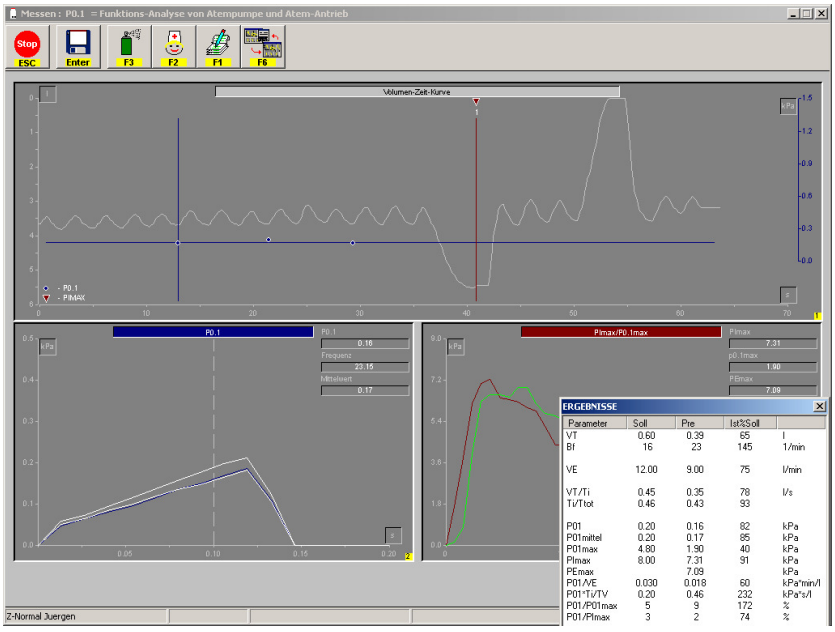
- → The measurement should use "running start" to ensure best results
- → In order to inhale the absolute maximum volume, the breathing frequency should not be too fast
- → According to known clinical practice, the optimum is about 30 cycles per minute
- → It is important that the patient uses a nose clip, forms a tight seal around the mouthpiece with his or her lips and breathes maximally throughout the recording phase

4.4.4 End Of Measurement And Evaluation

Selection of the 

Icon or pressing the [Enter] key ends the measurement and displays the computed results.

4.4.5 MVV Window After Measurement



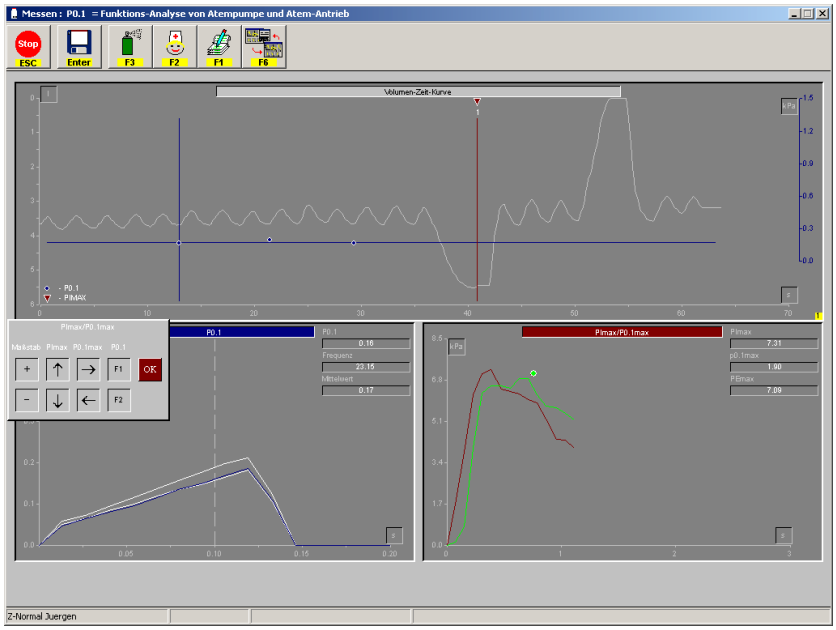
Selecting the 

Icon or pressing the [F6] key toggles the results window on and off.

The content of the results window can be configured by double clicking on the results window. This leads into the parameter selection window, where parameters can be selected to be displayed in the results window for future tests. The selection can be changed at any time.

4.4.6 Post Processing

A mouse click in one of the three sub windows opens a small post processing window. The post processing windows of all three sub windows are almost the same. A function is performed by clicking on the appropriate symbol.



- ► Click on **+** or **-** to change the scale.
- ► Up arrow and Down arrow icons manually change PImax value of the measurement set
- ► left arrow and right arrow icons selects a P0.1max value manually.
- ► selecting the **K** icon deactivates the selected P0.1 curve.
- ► Using the [F1] and [F2] keys allows manual determination of a PEmax value of the measurement.

4.4.7 Co-operation

It is hard to determine if the patient co-operates fully. It is up to the technician to carefully observe the patient and motivate him/her, to obtain accurate results.

Important: The patient must try to inhale to maximum after his/her maximum exhalation**.**

4.5 P0.1, P0.1max, PImax, and PEmax

Caution: To perform this test, the shutter unit must be connected properly to the Flowhandy ZAN100 USB. Refer to chapter 1 for more information**.**

Note: These tests depend on good co-operation of the patient. It is important to explain every aspect of the test to the patient BEFORE the test starts and make sure the patient is willing to co-operate.

4.5.1 Definitions

P0.1	is the pressure measured at the mouth 100ms after inhalation starts during a tidal breath manoeuvre. This pressure represents the effort that the patient has to make in order to breathe normally.
P0.1max	is the pressure measured at the mouth 100ms after inhalation starts after a maximum exhalation manoeuvre.
PImax	is the maximum pressure of **in**halation which the patient can cause.
PEmax	is the maximum pressure of **ex**halation which the patient can cause.

P01max and PImax require an identical breathing manoeuvre and will be measured simultaneously.

4.5.2 Measuring P0.1

- ► The patient breathes normally.
- ► During exhalation, click on the corresponding symbol to start the measurement.
- ► When the next inhalation starts, the respiratory flow will be interrupted for 120ms

The pressure is registered 100 ms after inhalation starts. The pressure represents the effort a patient can make during normal breathing

4.5.3 Measuring P0.1max

- ► The patient breathes normally.
- ► By request, the patient **exhales maximally**.
- ► During exhalation, click on the corresponding symbol to start the measurement.
- ► The patient is requested to inhale as powerfully as possible.
- ► When the next inhalation starts, the respiratory flow is interrupted for 1 –2 seconds.

The pressure is registered 100 ms after inhalation starts. This pressure represents the maximum effort, which the patient can make.

4.5.4 Measuring PImax

- ► The patient breathes normally.
- ► By request, the patient **exhales** maximally.
- ► During exhalation, click on the corresponding symbol to start the measurement.
- ► The patient is asked to **inhale** as deeply as possible.
- ► When the next inhalation starts, the respiratory flow is interrupted for 1-2 seconds.

The maximum pressure after interrupting the respiratory flow is registered.

P01max and PImax require an identical breathing manoeuvre and will be measured simultaneously.

4.5.5 Measuring PEmax

- ► The patient breathes normally.
- ► By request, the patient **inhales** maximally
- ► During inhalation, click on the corresponding symbol to start the measurement.
- ► The patient is asked to **exhale** as deeply as possible.
- ► When the next inhalation starts, the respiratory flow is interrupted for 1-2 seconds.

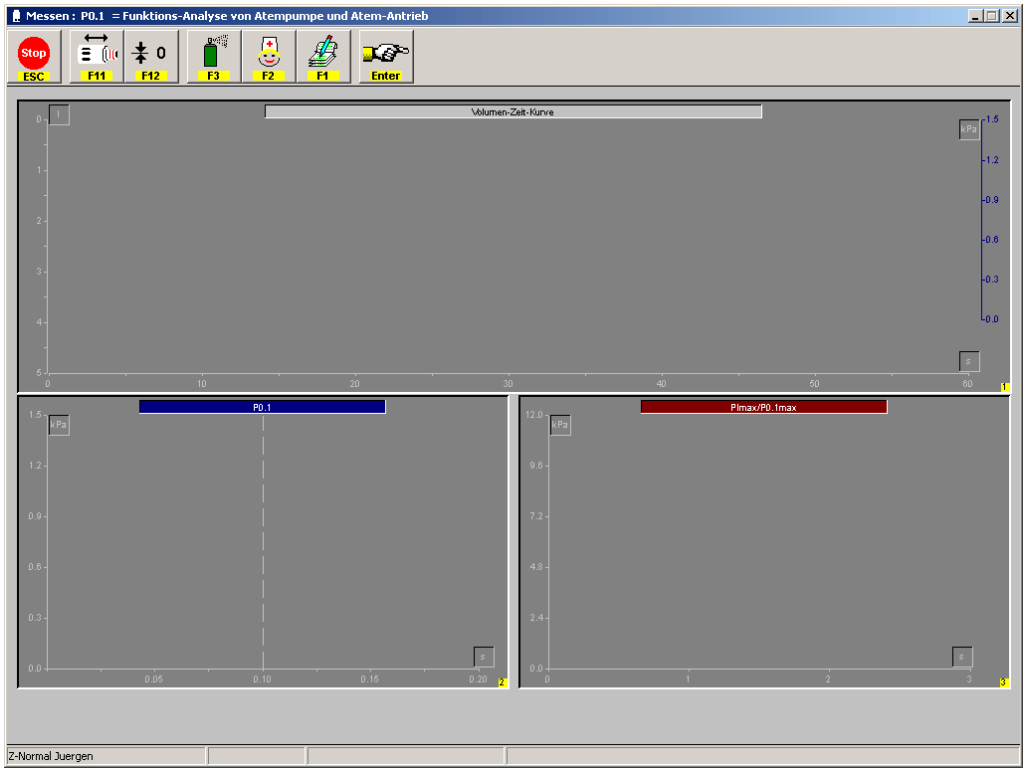
The maximum pressure after interrupting the respiratory flow is registered.

4.5.6 Performing the P0.1 Measurement

Start measurement by selecting the P0.1 Symbols 

in the MEASURE menu.

Screen Before Measurement



Symbol Definitions

	Stop the measurement and exit the programme
	Define the user
	Demonstrate the shutter
	Enter comments
	Reset the zero point. (Patient must not breathe through the sensor.)
	Start the measurement
	Select a medication.

Note: During resetting the zero point, the patient must NOT breathe through the sensor. After reset, the patient applies the nose clip and forms a tight seal with his/her lips around the mouthpiece.

► Start the volume recording by selecting the 

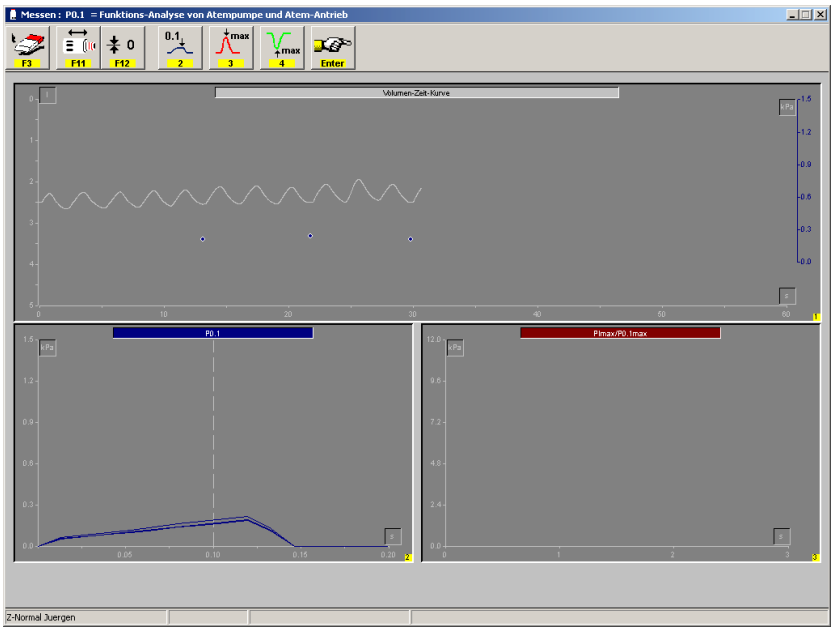
icon or pressing the enter key.

► The patient breathes normally.

► During tidal breath the measurement is started by randomly selecting the P0.1 Symbol 

.

► The device will automatically interrupt the flow 120ms after the beginning of the next inhalation and records the mouth pressure



After every 2-4 tidal breaths this manoeuvre is repeated at least 5 times.

4.5.7 Performing PEmax and PImax Measurement

4.5.7.1 P0.1max and PImax

To measure P0.1max and PImax, the patient is asked to exhale as deeply as possible.

- ► During deep exhalation, select the PImax icon .
- ► The device will automatically interrupt the flow after the beginning of the next inhalation for 2 sec. and records the pressure at the mouth
- ► The patient is asked to inhale during this time to inhale as powerfully as possible.
- ► Repeat this manoeuvre at least 3 times, to obtain acceptable results.

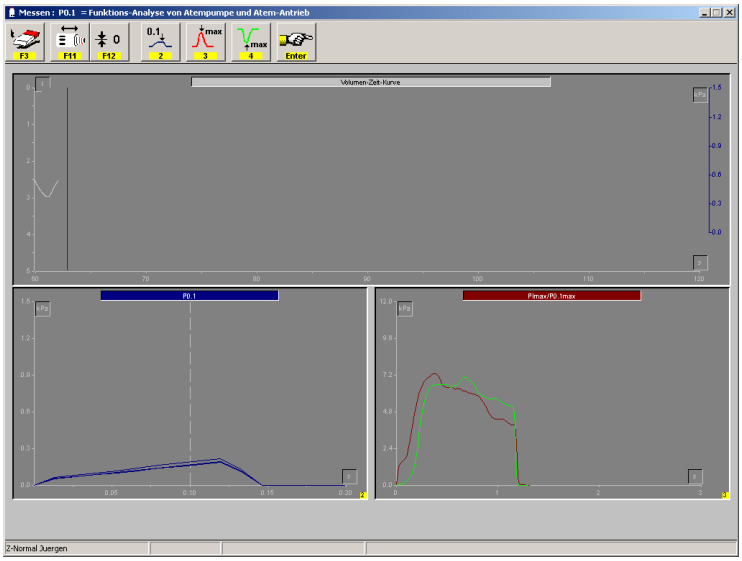
Important: Between each PImax interruption wait for a minimum 5 tidal breaths to give the patient a rest.

4.6.5.1 PEmax

The PEmax manoeuvre is inverse to the PImax manoeuvre. The patient starts with maximum inhalation

- ► During deep inhalation, select the PEmax icon .
- ► The device will automatically interrupt the flow after the beginning of the next exhalation for ca. 2 sec. and records the pressure at the mouth.
- ► The patient is asked to exhale as powerfully as possible.
- ► Repeat this manoeuvre 3 times or more.

Important: This test should be repeated after a short pause of minimum 5 tidal breaths to give the patient a rest.



4.5.7.2 Additional recommendations

In most cases, the patient is a little nervous before the measurement and breathes too deeply or too fast. If so, the patient's tidal respiration has to be corrected by demonstrating the appropriate breathing pattern.

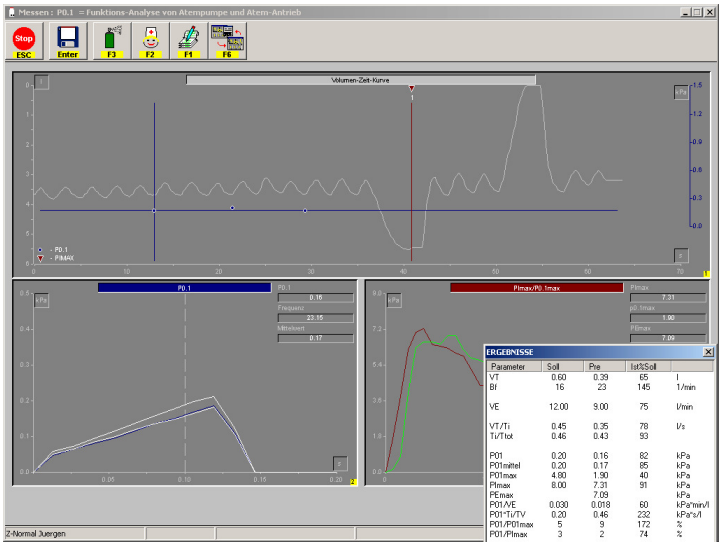
Important: P0.1 measurement is carried out during absolute tidal respiration.
The time of interruption during P0.1 measurement is limited to 120 ms, because the patient must not change his or her breathing pattern.
If possible, the interruption should be started unobserved by the patient.

Note: It is recommended to carry out the P0.1 measurement before the PImax measurement, because after maximum effort, tidal respiration will not be regular.

4.5.8 Completing the P0.1 Measurement and Analysis.

By re-selecting the 

symbol, the measurement will be completed, and the results will be calculated and inserted.



With this Button you can toggle the results table on and off..

4.5.8.1 Parameter Selection

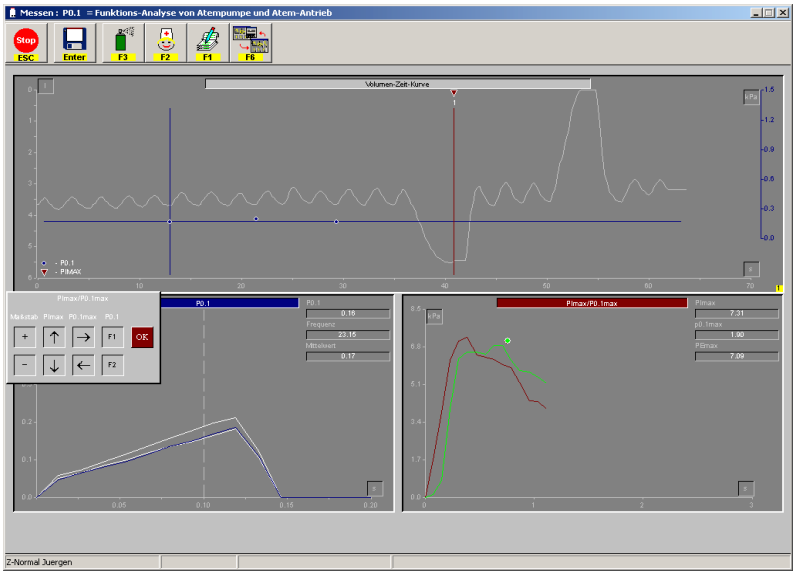
With a double click on the results window you can open the parameter selection window. Select the relevant parameters from the parameter list. They will be shown in the results window from now on.

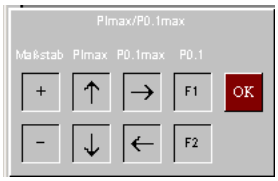
Refer to the "parameter selection" paragraph in the "SVC Measurement" chapter for more details

4.5.9 Editing a P0.1 Measurement

By clicking on one of the three measurement screens, a small window for editing a measurement is displayed. These windows will differ a little from each other.

Click on the appropriate symbol to perform the desired function.





- **+** Increases the scale of the graphic.
- **-** Decreases the scale of the graphic.
- ↑ If more than one manoeuvre has been performed, use this icon to scroll up to the previous manoeuvre.
- ↓ If more than one manoeuvre has been performed, use this icon to scroll down to the next manoeuvre.
- ← Use this icon to move left to position where the measurement should be analysed, manually overriding the computer selection.
- → Use this icon to move right to reposition where the measurement should be analysed, manually overriding the computer selection.
- **K** Deletes the selected P0.1curve.

4.5.10 Co-operation

The P0.1 measurement does not require the patient to perform any controlled manoeuvres, however for P0.1max, PEmax, and PImax measurements, the patient needs to perform breathing manoeuvres for the test to be measured correctly.

Important: After deep exhalation, the patient must try to inhale with maximum effort.

To obtain valid results, the interruption should be started unobserved by the patient, so the patient does not recognise or react awaiting the interruption.

4.6 Rhinomanometry

4.6.1 Principles

Rhinomanometry measures the flow resistance of the nose.

The flow in one half of the nose is recorded and compared to the pressure which is measured in the second half of the nose.

We differentiate between the anterior and the posterior measurement.

4.6.1.1 Anterior Measurement

The anterior measurement records the pressure of both nasal tubes.

The pressure measurement is done while one side is blocked with a nasal tip or a foamed plastic.

The nasal tip or adapter is connected to the sensor by a flexible tube.

The patient breathes through the open half of the nose while the flow is measured with the sensor.

The blocking nasal tip or adapter is connected through a tube to the sensor on the rear side of the Flowhandy ZAN 100 USB. Now the patient breathes with a closed mouth through the open part of the nose while the flow is measured.

This measurement can also be performed using a mask (s.b.)

4.6.1.1.1 Using Nasal Tips

Connect the olive holder with the flow sensor on rear side of the Flowhandy.

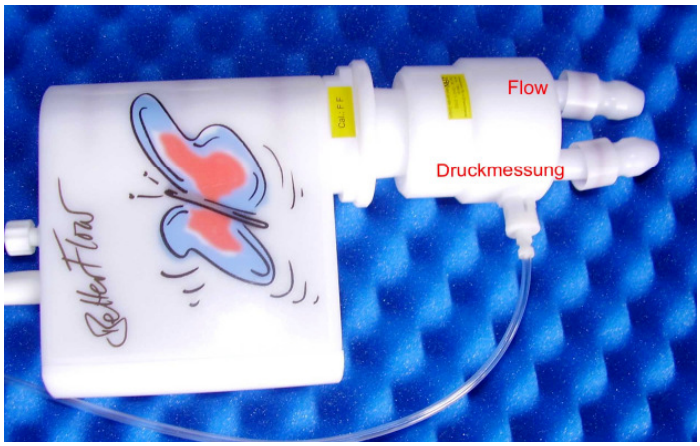
Place two clean, disinfected nasal tips on the olive holder. Put the olives in the nostril.

Now one of the olives is connected with a flow meter and one with a pressure meter.

The patient starts breathing through his nose.

The data of the nasal tip, connected with the flow meter will be recorded.

After the first measurement, the equipment is turned around to measure the other side of the nose.



Set-up for the use with nasal tips.

4.6.1.1.2 Using A Mask:

Even with a mask, the flow in one tube of the nose is compared to the pressure of the second tube.

Connect a new disposable nasal adapter to the internal tubing
There are different sizes available. Please choose the one which fits the best in the nostril.

Nasal adapter connected to the tubing

The mask is connected to the flow sensor and the tubing is connected to the pressure sensor on the back of the Flowhandy.

The Nasal adapter is placed in one nostril. Then the mask is placed over the patient's nose.

The patient breathes with a closed mouth. Again the flow and pressure are recorded. Placing the nasal adapter in the other nostril allows measurement of the second side of the nose.

This method is especially suited to children.

Important: Because the mask integrates nose AND mouth, it is important that the patient keeps the mouth shut and only breathes through the nose!

4.6.1.2 Posterior Measurement

Performing the posterior measurement the patient will also breathe through a mask, but the nose is not blocked. The pressure is measured in the mouth while the patient breathes through the nose.

To differentiate between the two nostrils, one can be blocked after the other to get results for each.

The patient takes the internal tubing between his lips. Use a new adapter tip for each patient. Make sure that the patient holds the tip firmly between his/her lips and the breath will only flow through his/her nose.

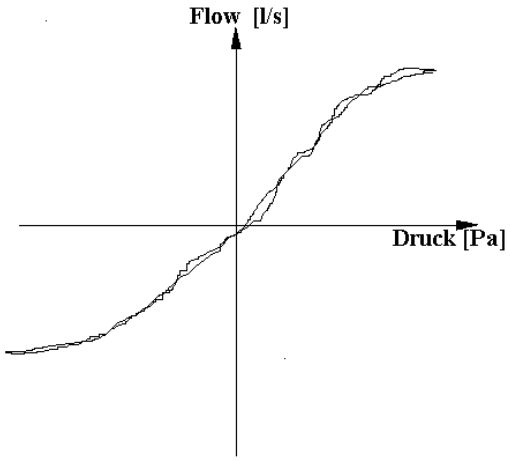
Important: After the measurement, all contaminated parts like olives, olive holder and flow sensor must be cleaned and disinfected according to the disinfection instructions. Do not reuse disposable parts like foamed plastic etc.

4.6.1.3 Important Parameters of Rhinomanometry

Short Name	Name	Meaning	measurement method
Flow 50	Flow at 50 Pa	Flow speed at 50 Pa pressure difference	Tidal breathe through one nostril
Flow 150	Flow at 150 Pa	Flow speed at 150 Pa pressure difference	Sa.
Res 50	resistance at 50 Pa	Nasal breath resistance at 50 Pa pressure difference	Sa.
Res 150	resistance at 150 Pa	Nasal breath resistance at150 Pa pressure difference	s.a.
Res 300	resistance at 300 Pa	Nasal breathresistance at 300 Pa pressure difference	s.a.

because the flow inside of the nose is always turbulent, the pressure difference shows a square function of the flow like : $P = f(F^2)$

The result shows a curve similar to this example.

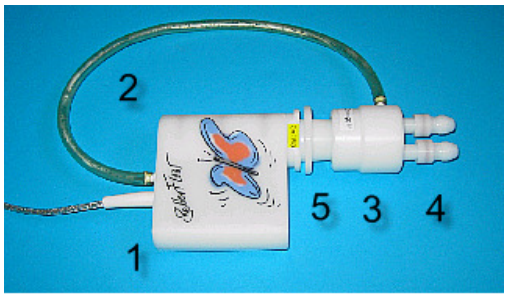


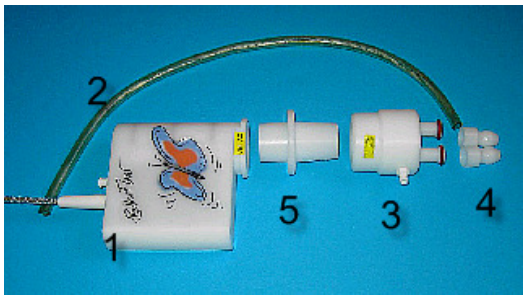
Because of the non linear relation between pressure and flow, the flow resistance is not constant and also depends on the pressure.

3 pressure values define this curve: 50 Pa, 150 Pa and 300 Pa. (s.a.)

4.6.2 Assembly And Connection Of The Parts

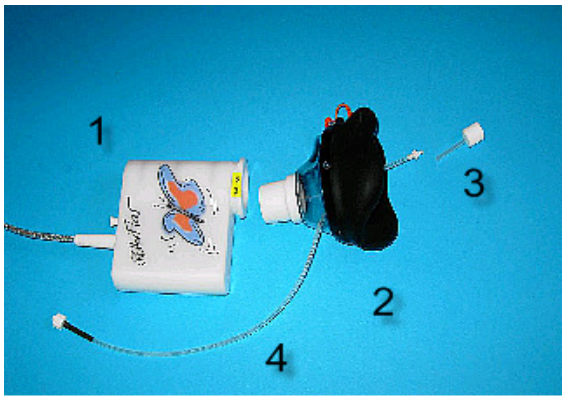
4.6.2.1 Using Olives

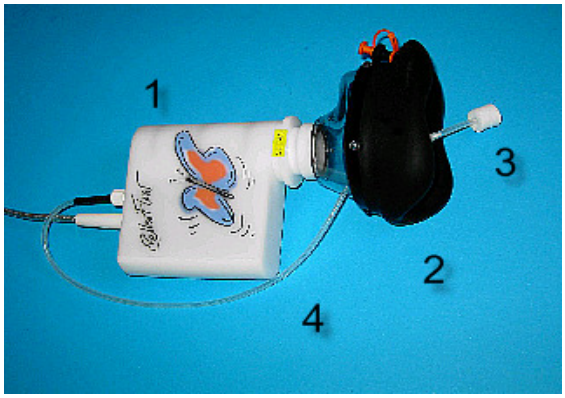




1. Flowhandy ZAN 100 USB
2. Tubing (connect to Olive holder (3) and Flowhandy ZAN 100 USB (1))
3. Put Olive holder on the adapter (5) and the Flowhandy ZAN 100 USB (1)
4. Put the 2 Olives (4) on the Olive holder (3)

4.6.2.2 Using A Mask





1. Flowhandy ZAN 100 USB
2. Put the Mask (2) on the Flowhandy ZAN 100 USB (1)
3. Connect the Nasal adapter (3) with the tubing to the Flowhandy ZAN 100 USB (1)
4. Connect the tubing to pressure sensor of the Flowhandy ZAN 100 USB

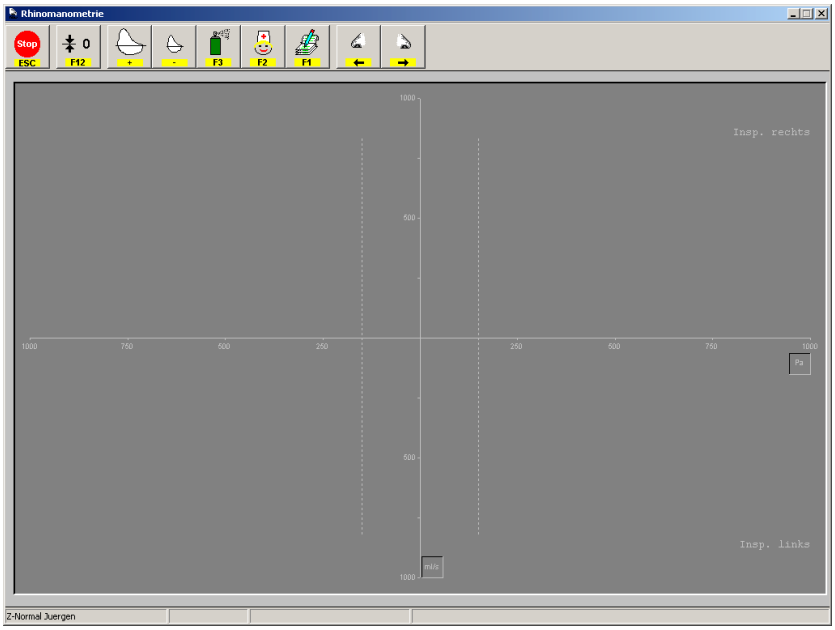
4.6.3 The Rhinomanometry Window before Measurement

Start the measurement by either selecting 

or 

according to your equipment.

You will then see this window



Symbol Definitions

	Cancel measurement		Select medication
	reset zero (patient must not breathe through the sensors)		Define user
	Zoom in		Enter remarks
	Zoom out		
	Start measuring the left part of the nose		Start measuring the right part of the nose

4.6.4 Performing Rhinomanometry

Note : Before starting the test, the patient should clean his nose properly in order to obtain reproducible results

Usually rhinomanometry does not require special co-operation from the patient. Sometimes the depth of the breath has to be adapted.

► Click on  or  will start measurement of the right or left nose.

You will see this hint

Please insert pressure olive into the right nostril

When measuring the left part of the nose, the pressure olive (or the foamed plastic of the nasal adapter) has to be positioned in the right nostril. The pressure olive is the one which is connected to the part of the olive holder where the tubing is connected.

To measure the right side of the nose, place the pressure olive into the left nostril.

► The patient starts breathing through his/her nose.

It is advisable to delete the first breaths from the display selecting the  icon or by pressing the F3 key, when the curves show wide variation.

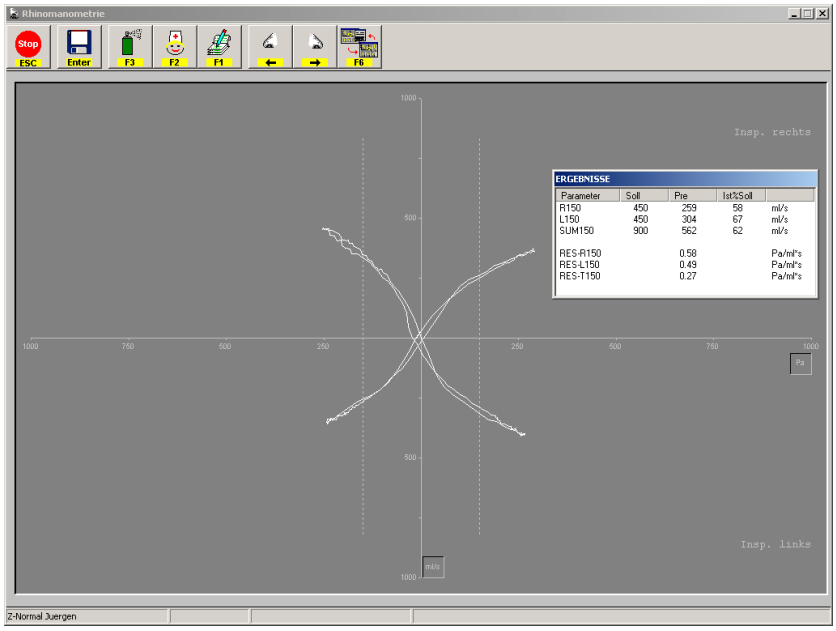
► Selecting the  icon or pressing the Enter key after 5 breaths, stops the measurement and displays the results.

► Re-selecting one of the icons  repeats the test, or initiates measurement of the other part of the nose.

► Selecting this icon 

or pressing the Enter key when the result window is up, saves the results and ends the test.

4.6.5 The Rhinomanometry Window After Measurement



Symbol Definitions

Toggle result window on and off

Save data

4.6.5.1 Parameter Selection

With a double click on the result window you can open the parameter selection window. Select the relevant parameters from the parameter list. They will be shown in the result window from now on.

4.6.6 Special Recommendations

When using the mask, make sure that the mask is tightly connected to the patients face.

When using olives, make sure that they are pressed from below into the nostrils, and form a tight seal. They should not deform the nostrils. Different sizes of olives are available so find matching pairs.

Two vertical lines mark the 150 Pa pressure on the screen.

The patient should breathe in a relaxed manner, but the dotted lines need to be reached or passed.

If the S curves do not reach these marks, the patient has to be asked to breathe deeper.

4.7 Measurement of CO Diffusion and Residual Volume

4.7.1 Basic Principles

The primary function of the respiratory system is gas exchange. Oxygen is transported from the environment through the lungs into the blood, while simultaneously carbon dioxide is released.

The inhaled air should distribute evenly throughout the lungs and oxygen, once in the alveoli, must diffuse through the alveolar-capillary membrane into the blood.

The effectiveness of gas exchange is mainly influenced by three factors:

1. distribution of air in the lungs,
2. perfusion of the lungs,
3. condition of the alveolar membranes.

There is a volume of air that remains in the lung even after a maximal expiration. Several diseases increase this residual volume and create an imbalance of actively exchanged air and the total volume of the lung. This will reduce the effectiveness of breathing.

Measurement of the diffusion capacity and the residual volume therefore give an estimation of the effectiveness of respiration.

4.7.1.1 Purpose of CO Diffusion Measurement

Carbon monoxide diffuses across the lung membrane in a similar way to oxygen. It resembles oxygen in solubility and molecular weight and it binds to the same site on the haemoglobin molecule as oxygen but with a much greater binding affinity. Baseline levels of carbon monoxide in normal, non-smokers are very low. This allows us to easily measure the amount of inspired and, after a breath hold, expired carbon monoxide making possible the calculation of the diffusion capacity or transfer factor.

4.7.1.2 5.2.1.2 Purpose of the RV Measurement

The residual volume is the volume in the lung which can not be expired. Up to a particular level this is physiological. This volume will increase in some diseases. Measuring the residual volume is a good way to estimate the severity and progress of the disease.

4.7.1.3 Measurement Principle

A test gas consisting of known concentrations of carbon monoxide (CO), and methane (CH_4), is inhaled by the patient. Methane is an inert gas and is only diluted by the residual volume. Both methane and carbon monoxide are equally diluted by the residual volume. A further decrease in the expired concentration of carbon monoxide is due to its diffusion across the lung membrane. From the concentration of inspired and expired gases, the transfer factor and residual volume can be calculated.

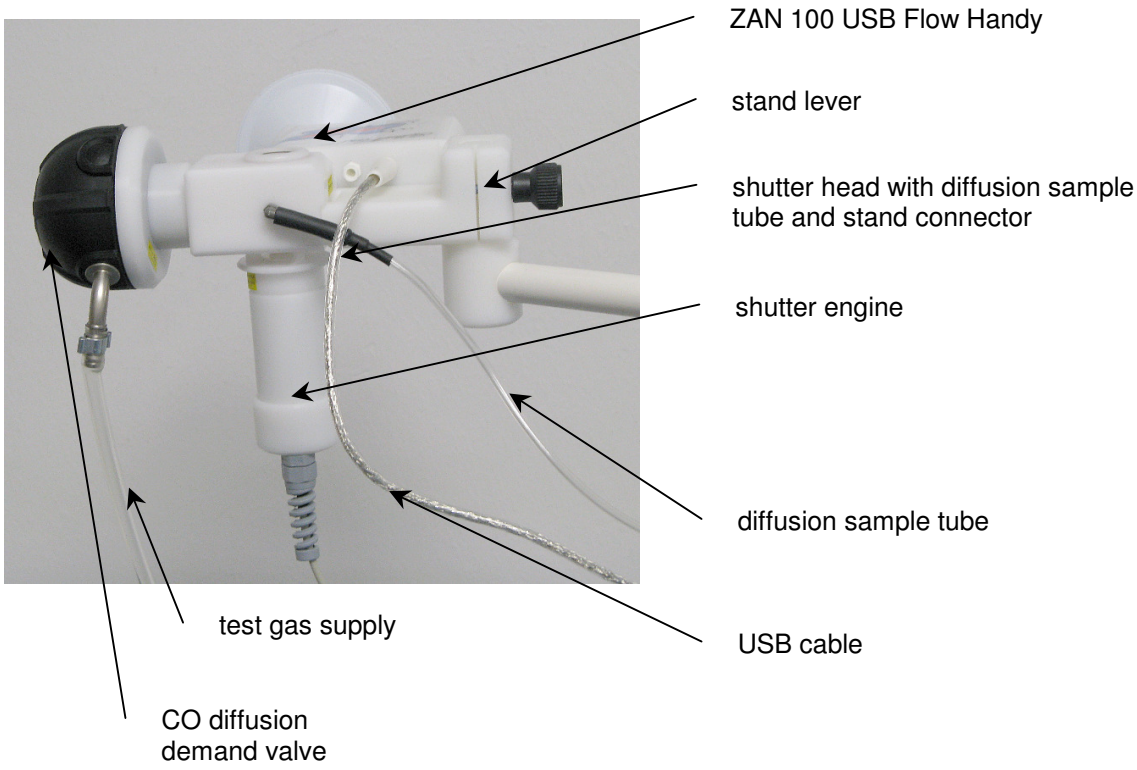
The transfer factor and residual volume are also calculated using the Fast Space balancing method. This method takes the total expiratory gas flux into account and is based on the principle that inhaled inert gas volume must equal exhaled inert gas volume plus residual inert gas volume.

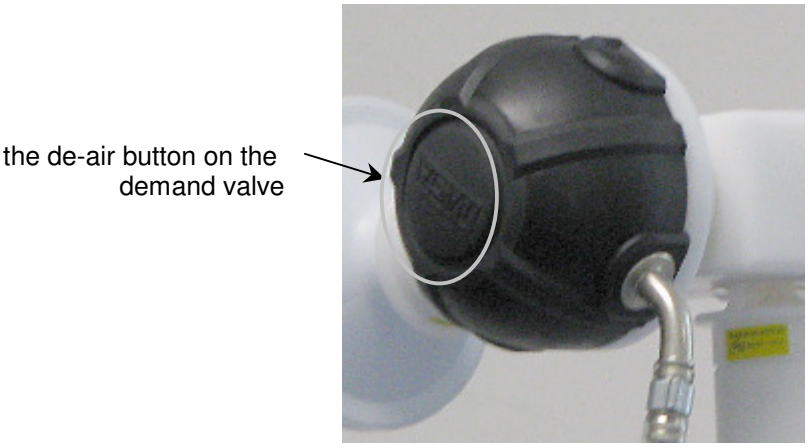
The fast response of the multi gas analyser is utilised and the exhaled methane concentration is plotted against lung volume. Distribution disease is clearly indicated by the shape of this graph.

Literature: H. J. Brandt, J. Bender, R. Lodenkämpfer and E. Wies. Balancing of a "fast space" by means of an alveolar mixing index. Diseases of the Respiratory Tract and Lung, Volume 4, No 3 1978.(p160-168)

4.7.2 Performing the Measurement

4.7.2.1 Assembly of the Device





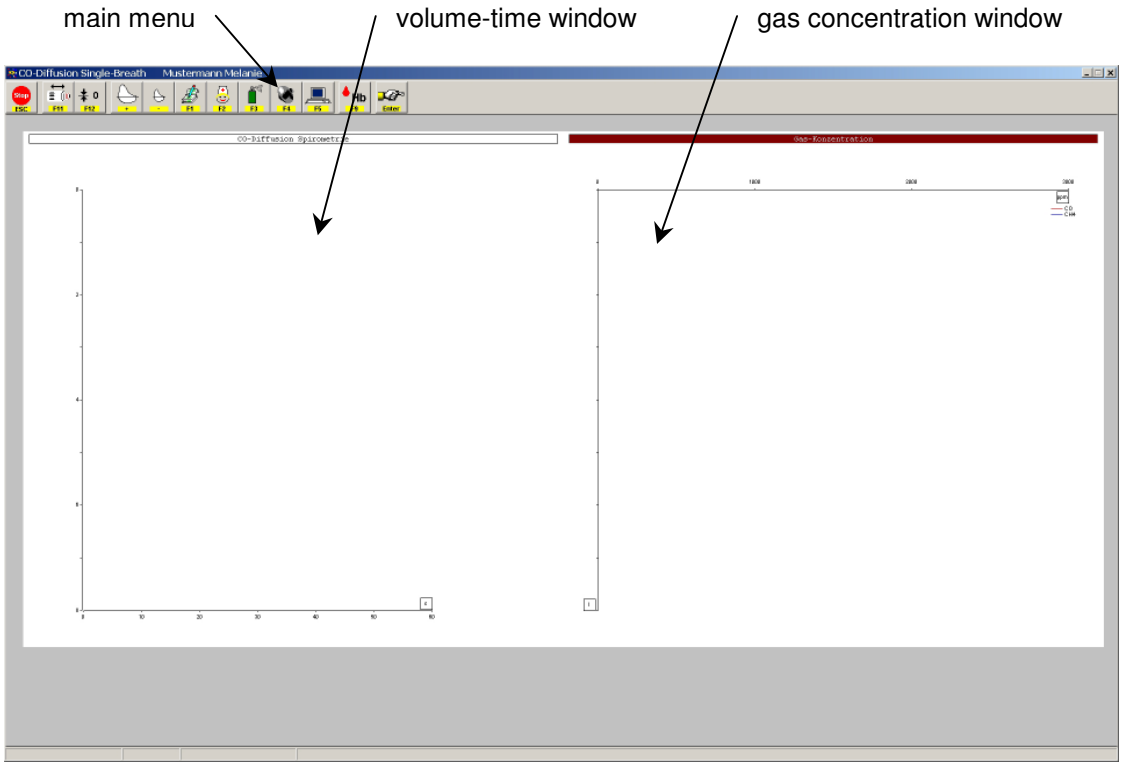
On the back side of the demand valve is a button integrated into the black cover. It is used to flush ? the system after changing the gas cylinder or in case the valve has to be disassembled for disinfection.

4.7.2.2 Structure of the Measurement Programme

4.7.2.2.1 The Master Screen

After starting the programme, the master screen is displayed. A timer and additional menu options appear in the measurement screen.

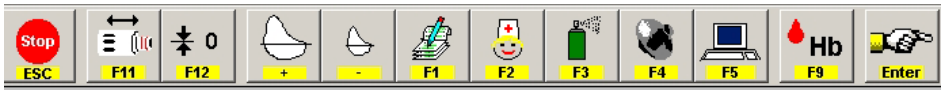
4.7.2.2.1.1 Structure



4.7.2.2.1.2 Menus

The main menu provides access to common functions of the CO diffusion measurement. The contents of the menu are different before and after the measurement. Only valid functions are displayed.

Menu before Measurement:



Menu after Measurement:

Symbol definitions

Select this icon or press the [ESC] key to stop the measurement and exit the program.

Select this icon or press the [F2] key to change the user.

Select this icon or press the [F9] key to input the actual Hb and HbCO concentration.

Select this icon or press the [Enter] key to start the measurement.

Select this icon or press the [F11] key to trigger the shutter.

Select this icon or press the [F3] key to select the medication.

Select this icon or press the [F12] key to reset the zero offset. (Patient must not breathe on the mouthpiece!)

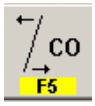
Select this icon or press the [F4] key to define type of mouthpiece and filter. (Deadspace.)

Select this icon or press the [+] key to increase scale.

Select this icon or press the [-] key to decrease scale.

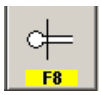
Select this icon or press the [F1] key to enter comments.

Select this icon or press the [F5] key to enter Set-up.



Select this icon or press the [F5] key to start CO edit mode. (Fast Space.)

Select this icon or press the [F4] key to start the inert gas edit mode. (Fast Space.)



Select this icon or press the [F8] to start residual volume edit mode.

Select this icon or press the [F6] key to toggle result window.

Select this icon or press the [F8] key to start report printing.

Select this icon or press the [F9] key to save the entry.

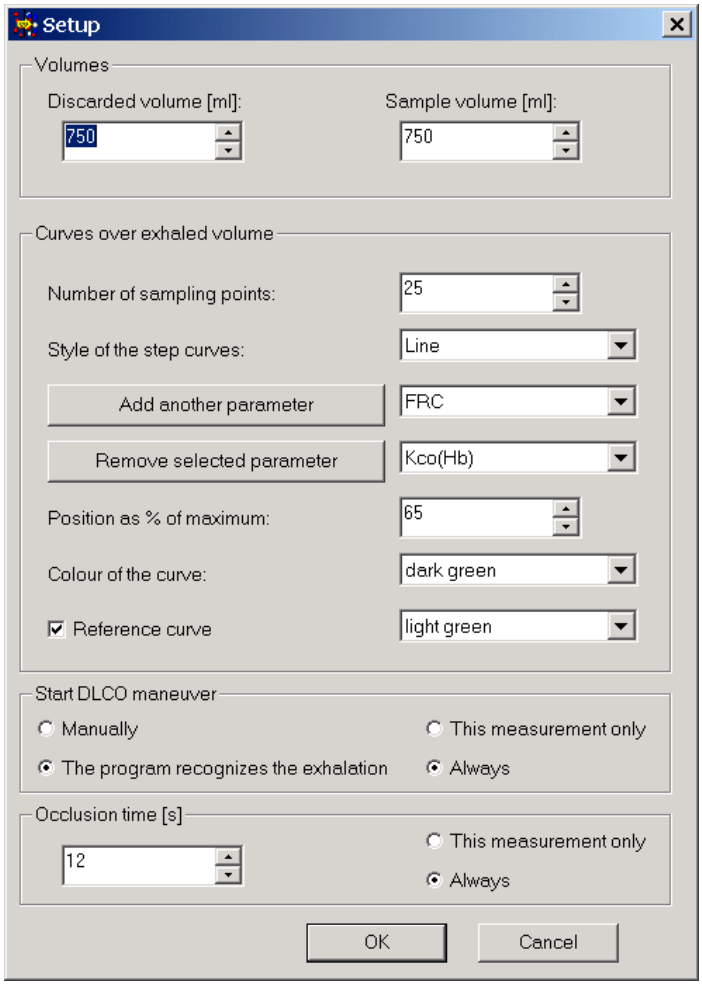
4.7.2.2.2 CO Diffusion Set up [F5]

Pressing the [F5] key or pushing the 

button opens the CO diffusion test set up dialogue. This dialogue allows to change the display and a few test parameters to be modified either for the next following test or permanently.

The dialogue is organised in four sections.

- Volumes :
  modify the volume to be discarded before sampling and the volume to be sampled for measurement
- Curves over exhaled volume
  Add, remove or modify the display style of the displayed curves.
- Start DLCO manoeuvre
  select the starting mode for the measurement
- Occlusion time
  determine the time, the shutter keeps closed to let the testgas diffuse.



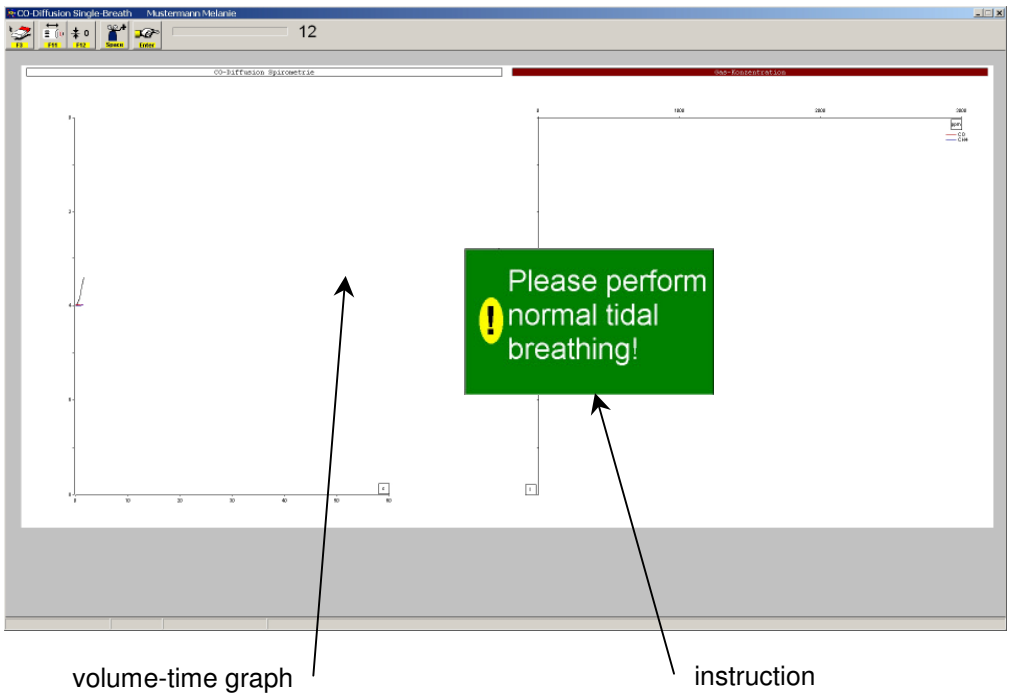
The " Curves over exhaled volume" allows to select the style and colour to be modified. To add a new curve to the display, pick a curve from the drop down list right from the "Add another parameter" and press the button. To remove a particular curve from the display, select the curve from the drop down list right from the "Remove selected parameter" and press the button.

The sections " Start DLCO manoeuvre" and " Occlusion time" have the option to be effective for the next measurement only ("This measurement only") or permanently ("Always").

4.7.2.2.3 The Measurement Screen

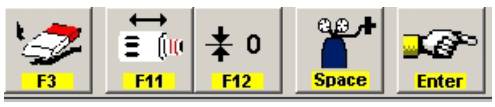
The Measurement screen looks very similar to the master screen. There's a different menu, a timer is displayed and instructions are given in the centre of the screen as guidance.

4.7.2.2.3.1 Structure



4.7.2.2.3.2 The Menu

The menu of the measurement screen contains the necessary controls to perform the measurement.



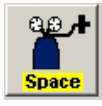
Symbol definitions

Select this icon or press [ESC] to erase the beginning of the test.

Select this icon or press the [F12] key to reset the zero offset. (Patient must not breathe on the mouthpiece!)

Select this icon or press the [Enter] key to start the measurement.

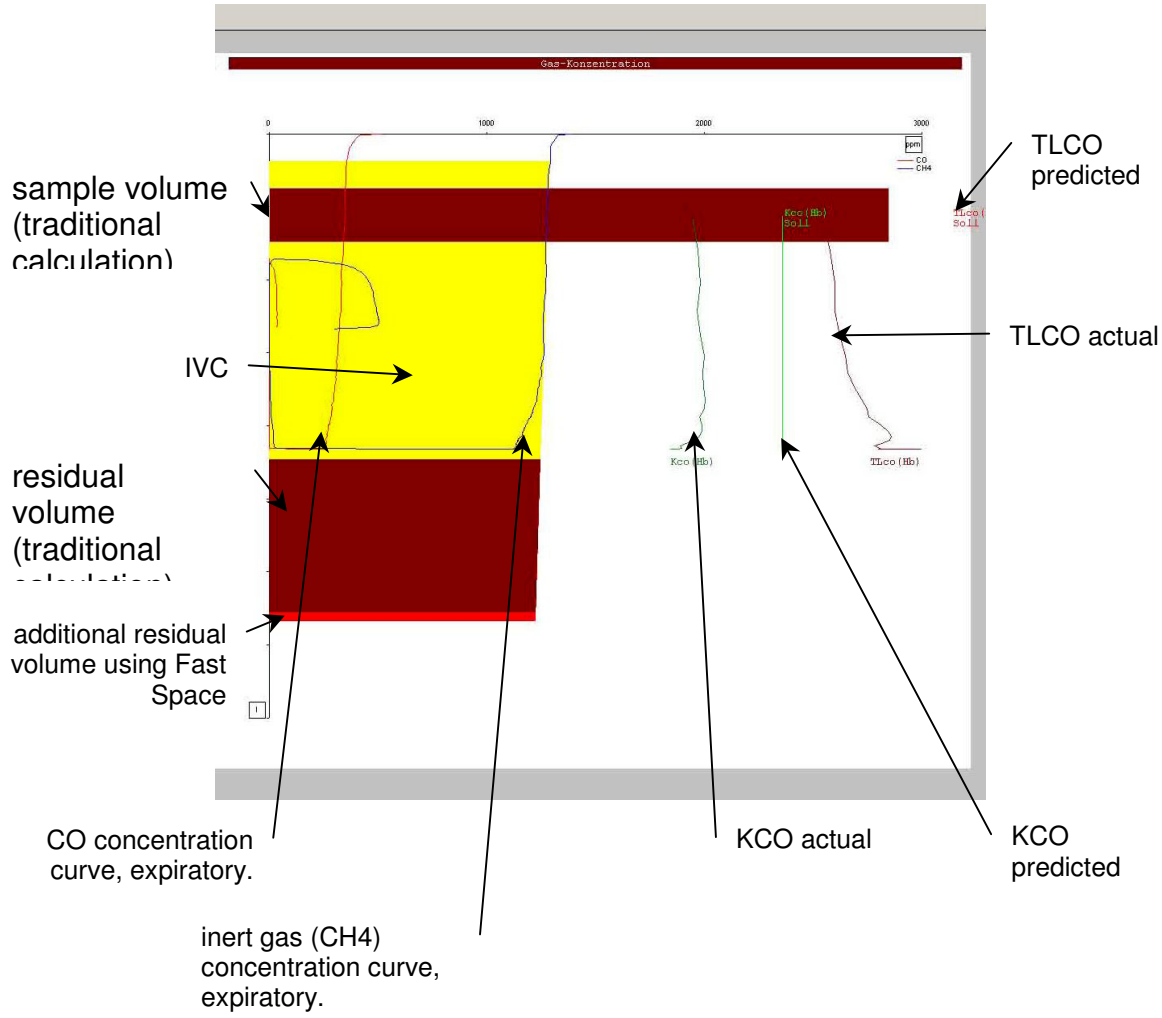
Select this icon or press the [F11] key to trigger the shutter.



Select this icon or press [Space] to open the demand valve and deliver the test gas.

4.7.2.2.4 The Result Window

After the measurement, the results in the form of a volume – concentration graph are displayed in the right half of the master window.

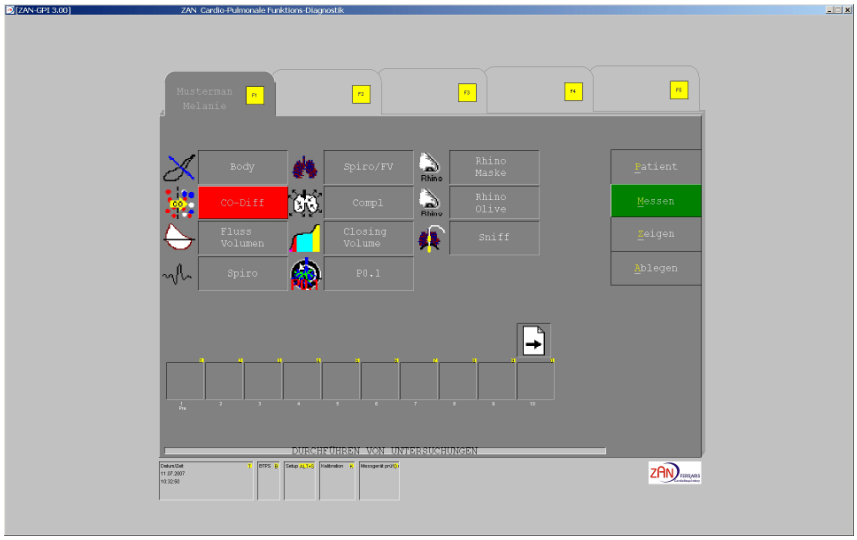


4.7.2.3 Performing the Measurement

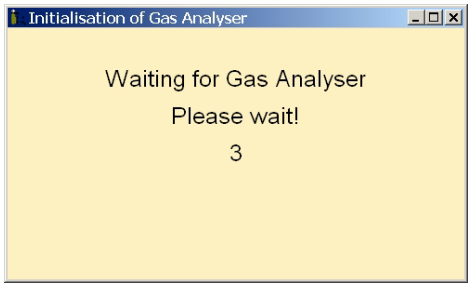
Caution : Patients who have consumed alcohol may produce erroneous results due to the fact that the gas analyser also responds to alcohol.

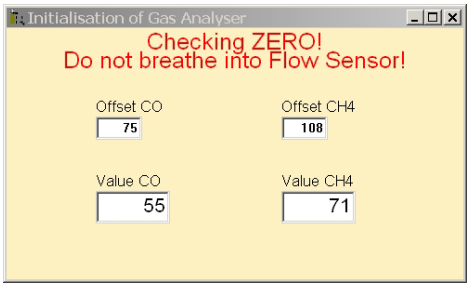
4.7.2.3.1 Start

After selecting a patient in the Main Screen, select the measure mode. The CO diffusion measurement programme is invoked by two clicks on the CO Diff button.

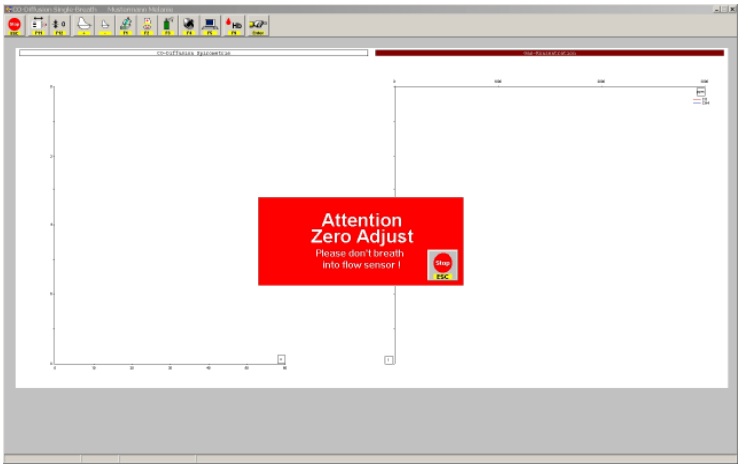


Before the programme starts, the analysers must be flushed and calibrated. During this time the user sees the messages below in the centre of the screen..





After initialisation the flow sensor must be adjusted to zero. A warning message is displayed during this time.



Caution: The patient must not breathe at the mouthpiece while the flow sensor is adjusted.

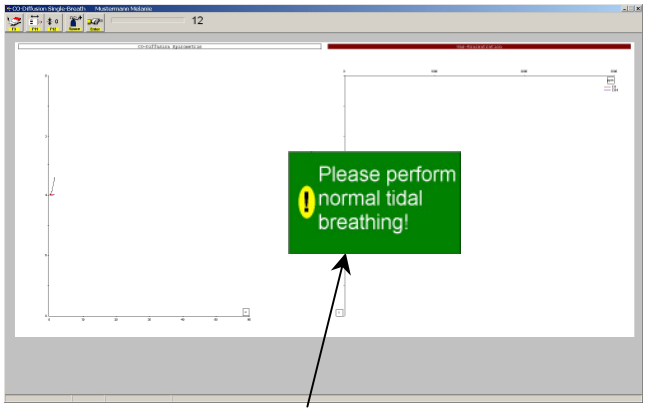
The system is ready, when the Zero Adjust message disappears.

4.7.2.3.2 Preparation

During the test, the patient is guided by the system with a sequence of instructions. This makes the execution of the test easier. The directions are displayed in a coloured window in the middle of the screen.

Select the 

button to start the test.



Direction

The measurement begins with regular tidal breathing. If the breathing trace is too erratic, clicking on the 

button or pressing the [F3] key restarts the sampling. After 5-8 tidal breaths the system begins with the test gas application.

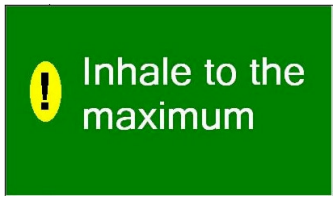
4.7.2.3.3 Test Gas Application

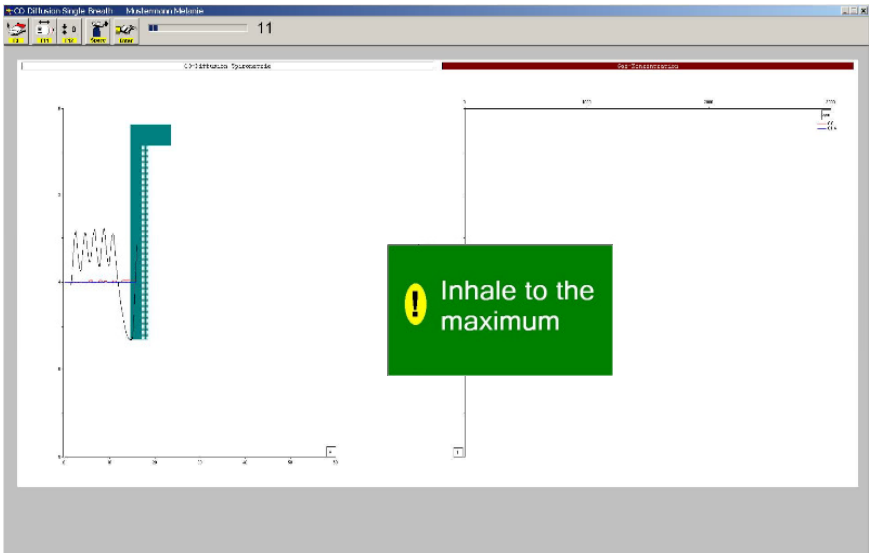
First, the patient is asked to breathe steadily all the way out.

Important : Inhalation and exhalation from the test gas must be performed steadily and without interruption!

The system displays the following messages:

After expiration, the patient is asked to maximally inhale the diffusion test gas..

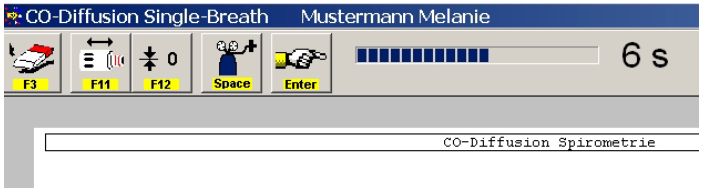




If an SVC has been saved, a green bar appears to indicate this patient's expected inspiratory flow rate and volume. This may also encourage the patient to achieve an adequate inspired volume.

After inhalation, the patient must hold their breath for a pre-set time ([F5]) to allow the CO to diffuse.

A countdown timer is displayed on the top bar of the window.

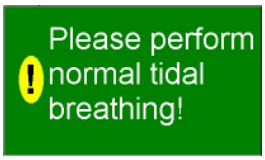


Note: If the patient is unable to maintain breath hold, click on 

or press the space bar to immediately reduce the breath hold time to zero and to open the shutter.

At the end of the breath hold time, the patient is again asked to steadily exhale until empty.

To complete the manoeuvre for the Fast Space calculation, the patient should return to normal tidal breathing.



The screen returns from the measurement screen to the master screen and shows the graphical results of the measurement. Numerical results may be displayed by pressing [F6].

Click on the 

button or press the [F9] key to save the results.

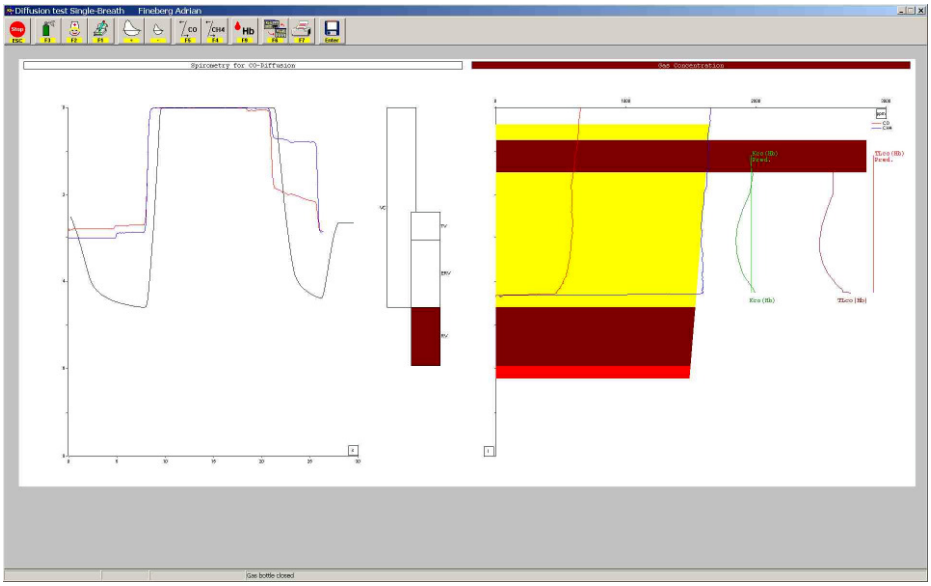
Caution : During breath hold, the patient should be encouraged not to breathe in or out against the shutter (but to relax against it) so as not to alter the intrathoracic pressure and pulmonary haemodynamics because this will affect the results.

4.7.2.4 Results

The results will be displayed graphically and numerically. From this view, the editing of the gas concentration result lines can be done (Fast Space.). The description on how this is done follows below.

4.7.2.4.1 Graphical Display of the Results

The standard view of the results is the graphical display. The left half of the window shows the volume, methane and carbon monoxide traces in different colours.

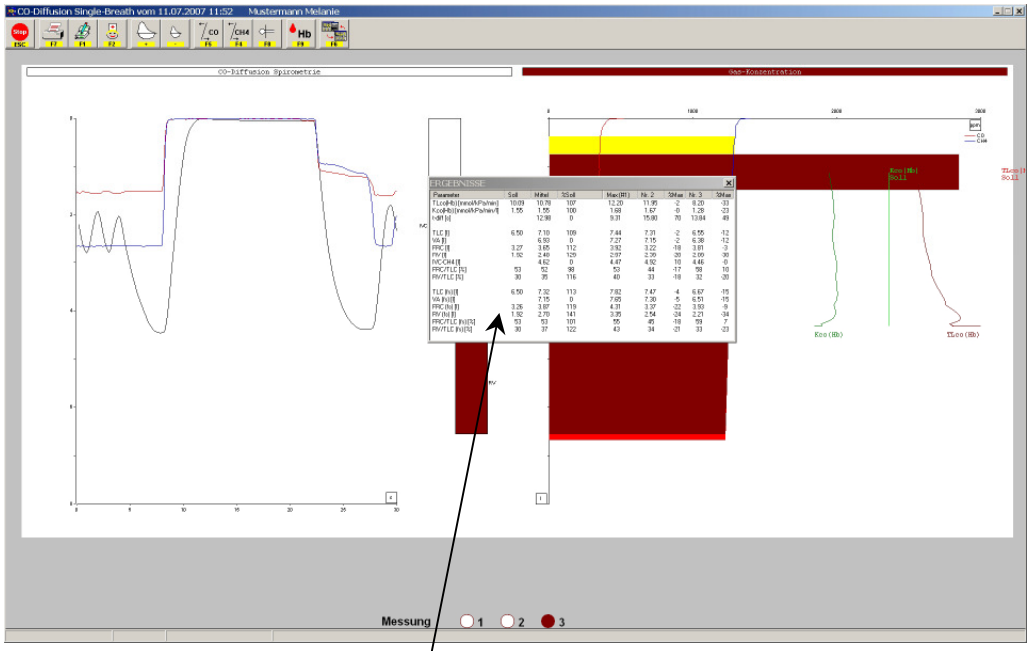


In the right part of the window is the volume-concentration graph showing the computed lung subdivisions and a graphical representation of TLCO and KCO.

4.7.2.4.2 Numeric Display

Selecting the 

buttons or pressing the [F6] key invokes the numeric display of the results (or hides it, if it is already visible)



ERGEBNISSE

Parameter	Soll	Mittel	%Soll	Max (#1)	Nr. 2	%Max	Nr. 3	%Max
TLco(Hb) [mmol/kPa/min]	10.09	10.78	107	12.20	11.95	-2	8.20	-33
Kco(Hb) [mmol/kPa/min/l]	1.55	1.55	100	1.68	1.67	-0	1.28	-23
t-diff [s]		12.98	0	9.31	15.80	70	13.84	49
TLC [l]	6.50	7.10	109	7.44	7.31	-2	6.55	-12
VA [l]		6.93	0	7.27	7.15	-2	6.38	-12
FRC [l]	3.27	3.65	112	3.92	3.22	-18	3.81	-3
RV [l]	1.92	2.48	129	2.97	2.39	-20	2.09	-30
IVC-CH4 [l]		4.62	0	4.47	4.92	10	4.46	-0
FRC/TLC [%]	53	52	98	53	44	-17	58	10
RV/TLC [%]	30	35	116	40	33	-18	32	-20
TLC (fs) [l]	6.50	7.32	113	7.82	7.47	-4	6.67	-15
VA (fs) [l]		7.15	0	7.65	7.30	-5	6.51	-15
FRC (fs) [l]	3.26	3.87	119	4.31	3.37	-22	3.93	-9
RV (fs) [l]	1.92	2.70	141	3.35	2.54	-24	2.21	-34
FRC/TLC (fs) [%]	53	53	101	55	45	-18	59	7
RV/TLC (fs) [%]	30	37	122	43	34	-21	33	-23

The average value of all selected efforts is displayed. Right clicking on a dot corresponding to an effort places a red cross over the dot and removes that effort from the average calculation. (Right clicking also removes the red cross.)

A left mouse click on the dot will display the graph of that effort.

4.7.2.4.3 Editing the Results

The regression lines for evaluation of the diffusion capacity and the residual volume are computed with numeric methods. Depending on the structure of the curves, the resulting line may differ from the optimum result and the user may want to reposition them. Every line can be moved manually.

Selecting 

button or pressing the [F9] key saves the edited values.

4.7.2.4.3.1 Editing the inert gas line to evaluate RV

Selecting the 

button or pressing the [F4] key loads the inert gas line (CH4 = Methane) in edit mode. The line is visible as a thicker green line. The green regression line can be adjusted by clicking on the end of the line with the left mouse button. If you press and hold the mouse button you can move the line along the exhalation curve

If the inclination or the position of the tangent has been changed, the gradient must be faded out again.

By clicking the 

icon again, the results will be re-calculated.

4.7.2.4.3.2 Editing The CO Diffusion Line

The CO-line is edited by selecting the 

button or pressing the [F5] key. The corresponding line can be moved with the mouse using the same method as the CH4 line above.

4.7.2.4.3.3 Editing The 'Closing Volume' Line (Optional)

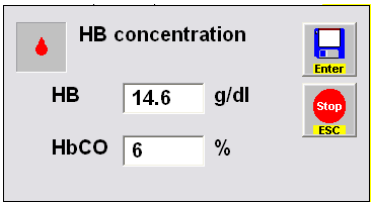
Selecting the 

Icon emphasises the CV line, which can then be moved with the mouse. This button is only visible, when the 'Closing Volume' option is installed on the system.

4.7.2.4.3.4 Considering blood data

Selecting the 

icon or pressing the [F9] key opens the blood data entry dialogue.



In addition to the hemoglobin value, now the HbCO value (carbonmonoxide blocked fraction of Hb) can be entered for more detailed evaluation. HbCO is respected in the calculation of the predicted values.

4.7.2.5 Important Information

The user should ensure that the patient keeps their lips tightly sealed around the mouthpiece and uses a nose clip throughout the test.

Caution : The patient must not try to breathe in or out against the shutter. This may cause the results to be under or overestimated.

Important : Patients, who have consumed alcohol should not be tested. The methane analyser is also sensitive to alcohol.

A methane concentration trace changing with the same frequency as the tidal volume is characteristic of a patient in whom alcohol is a constituent gas of their expiration.

Caution : Remember to allow sufficient time between tests for inhaled gases to be washed out. Testing too soon after the previous test will affect the results.

The concentrations of carbon monoxide and methane used in the CO diffusion measurement are very small (0.3%) and the equipment extremely sensitive, so the measurement should be performed with due care. Correct technique is important.

4.7.3 Addendum

4.7.3.1 Parameter Definitions

Acronym	Name	Meaning	Measurement Method.
TLCO	Diffusion Capacity or Transfer Factor	Rate of transfer of test gas between the alveoli and erythrocytes in the alveolar capillaries.	In a single breath, the test gas is inhaled and after a defined period of time, exhaled.
KCO	Transfer Coefficient	TLCO/VA Uptake of gas per litre of ventilated lung.	As above.
FRC	Functional Residual Capacity	Lung volume at end tidal respiration	Dilution of inert test gas.
RV	Residual Volume	Lung volume which can not be exhaled.	As above.
TLC	Total Lung Capacity	Maximum Volume of the Lung	
t diff	Diffusion Time		1/3 of inspiration up to 50% collected volume (Jones-Mead)
VA	Alveolar Volume	Volume participating in gas exchange	TLC - anatomical dead space

4.8 Closing Volume

Despite the presence of lung surfactant, at low lung volumes alveoli have a tendency to close. Alveoli in the lower parts of the lung have a greater tendency to collapse, due mainly to the weight of and pressure caused by overlying tissue. The lung volume at which alveoli collapse is called the Closing Volume (CV).

In young people, the CV is much less than the FRC. With age, the CV increases and the associated airway closure becomes significant as does the reduced ventilation of the lower lung.

4.8.1 What can be measured during the test?

4.8.1.1 CV

The CV is measured by the dilution of an inert gas.

There are two different but similar methods and both can be measured by ZAN:

1) Nitrogen wash-out method; and
2) Bolus (or inert gas wash-in) method.

1) During the *nitrogen wash-out* method, the patient must first expire to residual volume (RV). At this time, the alveoli of the closing volume are open and contain the normal concentration of approximately 77% nitrogen (N_2). Next the patient breathes in to total lung capacity (TLC) and fills his/her lungs with 100% oxygen (O_2).

In all of the patient's alveoli, the concentration of N_2 is slightly diluted by the addition of the O_2. When the alveoli of the CV close, the normal alveoli will remain open and the N_2 contained in these alveoli will continue to be diluted by the O_2. At the end of the inspiration, there is a relatively low concentration of N_2 in normal alveoli and a relatively high concentration of N_2 in alveoli of the CV.

Finally, the patient expires to RV. At first, the air from the normal areas of the lungs which have a low N_2 concentration is exhaled. Then, at the CV, the alveoli of the CV open and the N_2 concentration increases relatively abruptly; this corresponds to an upwards bend in the inert gas (N_2) concentration curve.

2) Methane (CH_4) (or helium (He)) is used by ZAN for the *bolus* method since the lungs normally contain no CH_4 (or He). First the patient must empty his/her lungs by expiring to RV and after doing so must then inspire to TLC. During this maximal inspiration of room air the system delivers a bolus of inert gas at a high concentration (0.3% CH_4).

During this test, all alveoli will initially contain a high concentration of CH_4 but as soon as the alveoli of the CV close, they will retain this high concentration of CH_4 while the gas in the remaining alveoli will be diluted by the room air. So, at the end of the inspiration, as in the N_2 washout method, there is a relatively low concentration of CH_4 in normal alveoli and a relatively high concentration of CH_4 in the alveoli of the CV.

Finally, the patient expires to RV. At first, the air from the normal areas of the lungs which have a low CH_4 concentration is exhaled. Then, at the CV, the alveoli of the CV open and the CH_4 concentration increases relatively abruptly; this corresponds to an upwards bend in the inert gas (CH_4) concentration curve.

4.8.1.2 Residual Volume (N2 washout only)

A second interesting parameter that can be determined with the CV measurement is the residual volume (RV).

With the calculated RV it is possible to determine further parameters, such as Closing Capacity (CC), FRC and TLC.

4.8.1.2.1 RV measurement

RV is determined during the CV measurement so no additional manoeuvre is required.

During the maximal inspiration, no N_2 is absorbed or transferred to the blood, the concentration of N_2 is only diluted by the RV. It is therefore possible to calculate the volume in the lungs at the beginning of inspiration, i.e. the RV, using the final and the initial concentrations of N_2 of this maximal inspiration. (The initial concentration of N_2 is approximately 77%.)

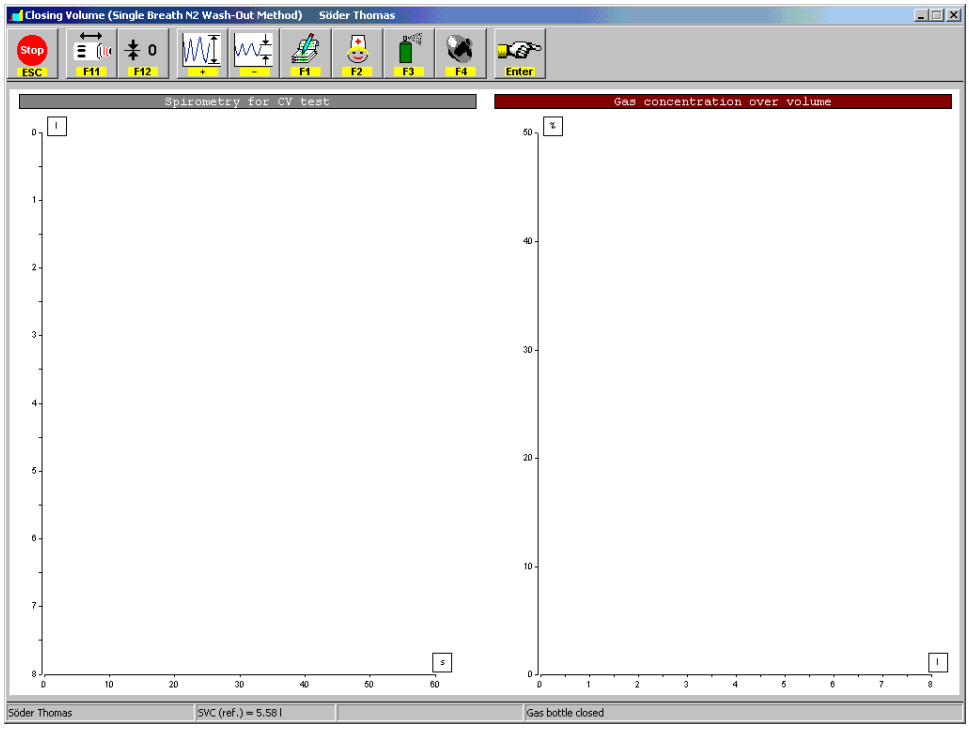
IMPORTANT: The determination of the RV, and the parameters CC, FRC and TLC derived from it, is only reliable when using the N_2 wash-out method. In the case of the CH_4 bolus method, a complete and exact synchronisation between volume and gas signals is required but is almost unachievable in practice.

4.8.2 Important measurement parameters of CV measurement

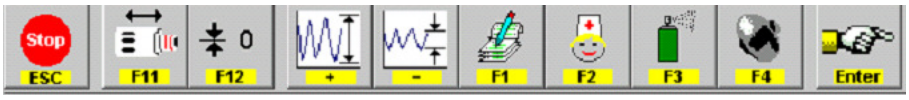
Short description	Description	Meaning
CV	Closing Volume	The volume in the lungs above which some alveoli close during an inspiration.
RV	Residual Volume	The volume remaining after a maximal expiration.
CC	Closing Capacity	CC = CV + RV
FRC	Functional Residual Capacity	The volume of air remaining in the lung at the end of a normal breath.
TLC	Total Lung Capacity	The volume in the lung after a maximal inspiration.

4.8.3 The CV program prior to the measurement

This window opens in the measurement mode after selecting the icon 



Description of the Symbols



	Cancel measurement		Enter operator
	Test shutter		Enter comments
	Set flow zero (no flow through flow sensor)		Increase scale (more details)
	Chose medication		Decrease scale (less details)
	Filter selection (see Chapter “Flow/volume measurement”).		Start measurement

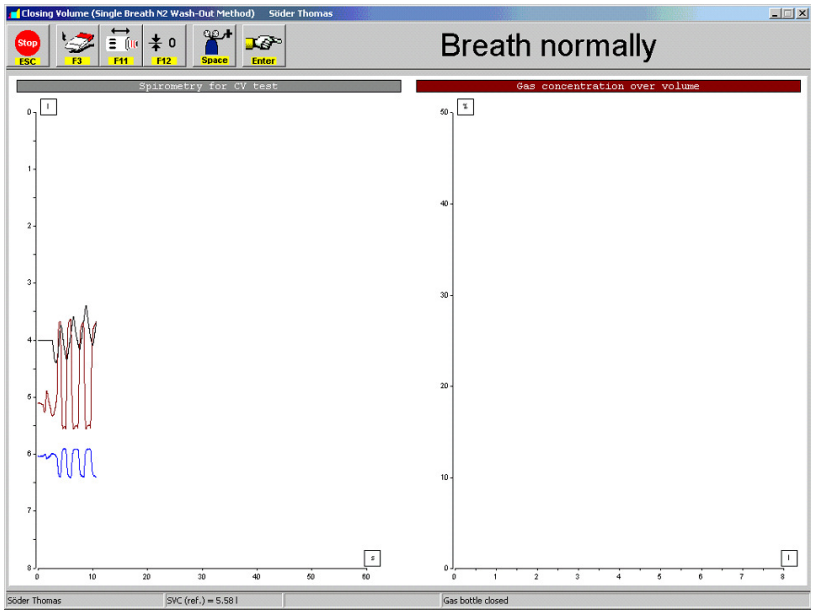
The keyboard can be used to activate these icons at any time by pressing the key highlighted in yellow. A short explanation of the function of each icon will appear when hovering the mouse over the icon.

4.8.4 Performing the CV measurement

1. The patient should sit in an upright but comfortable position, the height of the seat and stand should be adjusted accordingly.
2. Select the CV program before connecting the patient to the flow sensor.
3. Once the program has been selected the flow sensor must find its zero point. The warning screen below reminds the user to ensure there is no flow through the sensor at this time.

4. Connect the patient to the mouthpiece, attach a noseclip and ask them to breathe normally.
5. Press 

to start the measurement. The following screen will be displayed.



Meaning of the icons

Delete graph and restart

Test shutter

Set flow zero (no flow through flow sensor)

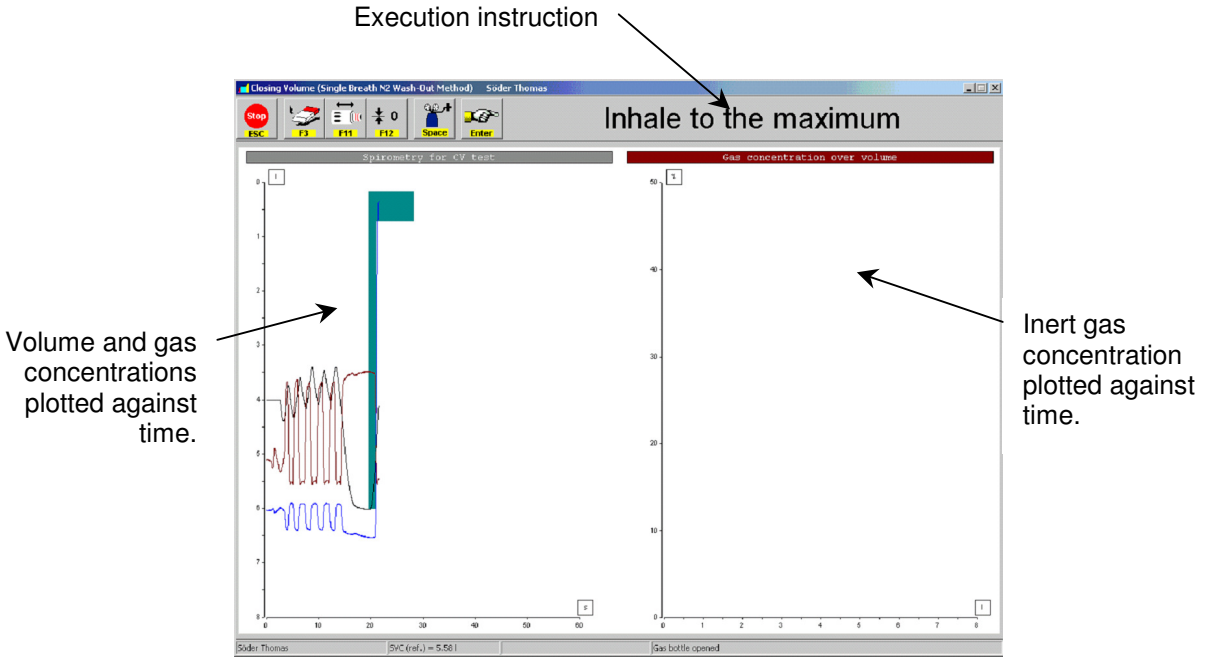
Release gas manually

Start manual evaluation

6. On the left of the screen shown below are the volume and gas concentrations plotted against time. In case of the N_2 wash-out method, the gases are O_2 and CO_2, for the bolus method, it is CH_4.

7. In the top right corner of the window, are instructions on how the patient should perform the test. Initially, the patient should breathe normally.

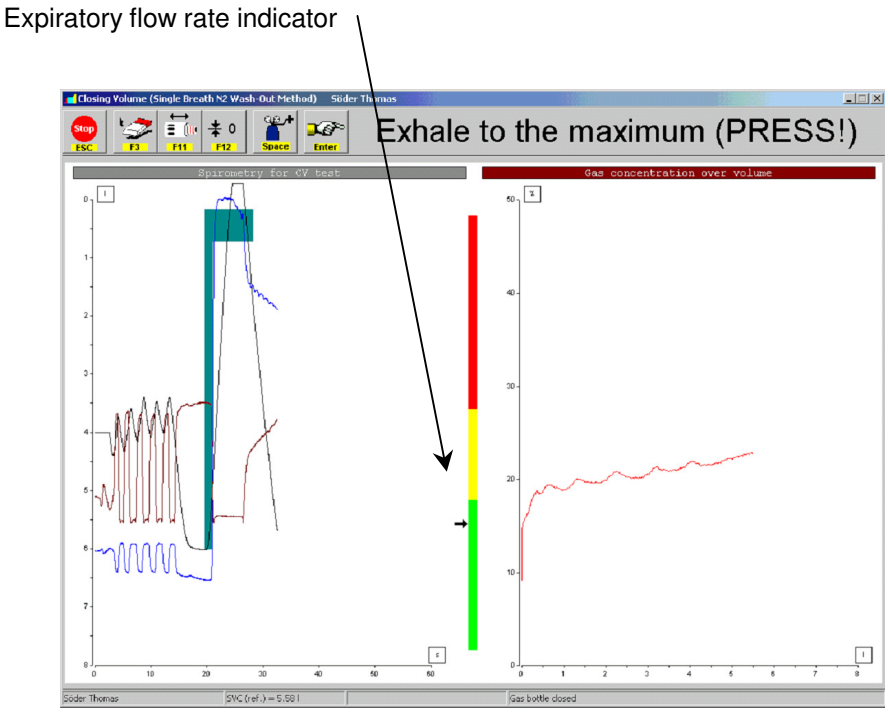
8. Next the patient should expire to RV. The system will automatically detect that the patient is empty and the gas will be released for the patient to inspire to TLC. The test gas will either be 100% O2 (N2 wash-out) or 0.3% CH4 (bolus).



9. Finally, the patient is asked to expire to RV. (No breath hold is required.) During this final part of the manoeuvre, it is important that the air is expired at a flow rate of no more than 0.5l/s. A coloured bar and pointer are located in the centre of the screen to guide the patient. When the pointer is in the green region, the speed is below the limit of 0.5l/s and is acceptable. In the yellow region the speed is slightly elevated and when the pointer is in the red region the speed is significantly too fast and the patient should be asked to expire more slowly.

IMPORTANT: When the patient maximally expires they must push hard to empty their lungs. If they do not, the typical 'CV bend' will not be evident.

The thick shaded bar in the left part of the screen indicates 90 - 100% of the vital capacity determined in the spirometry performed on the same day or, if no spirometry has been measured, it indicates 90 – 100% of the patient's predicted VC. It also suggests an appropriate rate of inspiration.



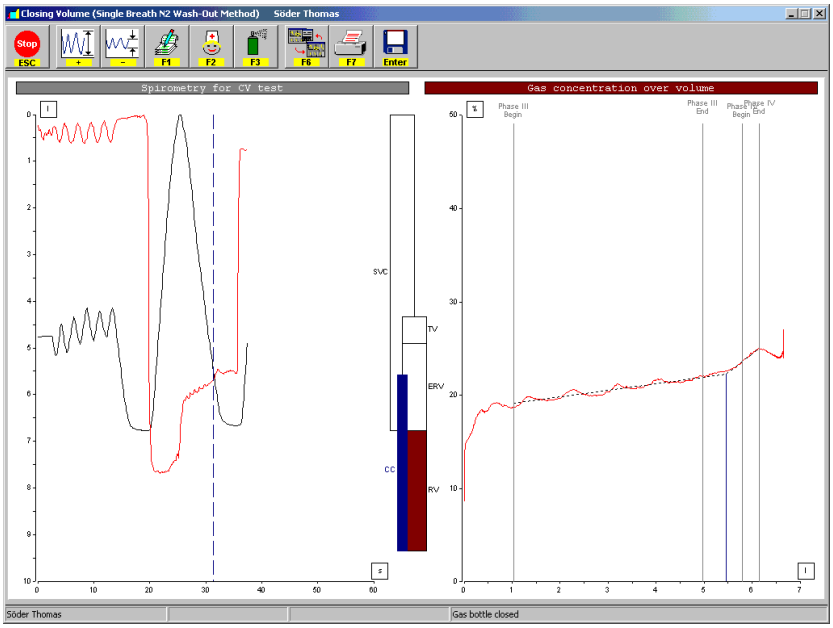
IMPORTANT: The patient must push hard to empty their lungs at the end of each expiration. If not, the typical 'CV bend' will be missing.

In the diagram on the right, the concentration of inert gas (N_2 or CH_4) is plotted against expired volume. The small waves, as shown in the figure, are attributable to the heart beat and are normal.

10. Once the patient has completed the final expiration to RV they should return to normal breathing or come away from the mouthpiece.

11. The program will automatically move to the analysis mode.

4.8.5 The CV program after the measurement



4.8.5.1 Meaning of the icons

	Cancel measurement		Enter operator
	Increase scale (more details)		Decrease scale (less details)
	Enter comments		Select medication
	Show/hide numeric results window		Save, end and print out measurement
	Save and end measurement		

4.8.5.2 Meaning of the curves

In the left hand graph, the spirometry and inert gas curve are plotted against time. The vertical blue dotted line indicates the time when the CV starts.

The graph on the right shows the inert gas curve plotted against expired volume. Additionally, four auxiliary lines ('cursors') are displayed which can be moved by dragging them with the mouse. The position of these four cursors is automatically calculated and generally they do not need to be moved.

Both cursors 'Phase III start' and 'Phase III end' border phase III, the plateau phase. A regression line, shown as a black dashed line, is calculated to describe the data bound in phase III. A regression line is similarly plotted to describe phase IV, the data bound by 'Phase IV start' and 'Phase IV end.

The start of the closing volume is at the intersection of the two regression lines.

If the program cannot calculate a regression line or if the gradient of phase IV is lower than the one of phase III, the closing volume will be set to zero.

To manually set the CV to zero, adjust the cursors so that the gradient of phase IV is lower than that of phase III.

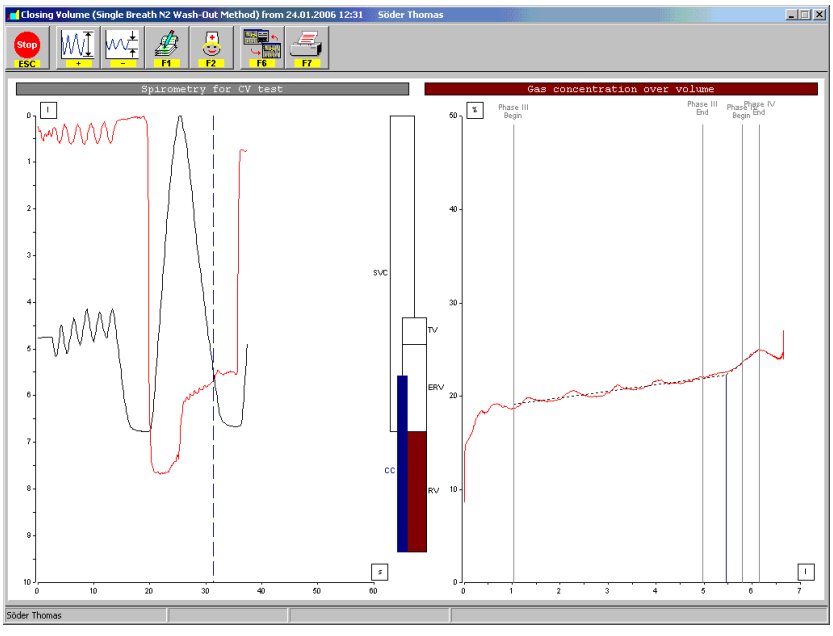
The bar graph in the middle shows clearly the individual lung volumes IVC, TV, ERV and RV as well as CC. The scale corresponds with the one of the spirometry diagram.

Important: Please note that the calculated value for RV only is reliable if you perform the N_2 wash-out method (not to the bolus method).

4.8.6 The CV program in the display mode (single measurement)

When displaying an individual measurement, the program is similar to the analysis phase of the measurement mode but has the following minor differences:

- The "medication" icon  is not shown
- The "save" icon  is not shown
- The "cancel program" icon  must always be used to exit the program. If changes have been made, you will be asked whether you want to save these changes or reject them.
- When the "operator" icon  is selected, the name of the person who performed the test is displayed but changes cannot be made.
- After choosing the "printing" icon  the program will not automatically end.



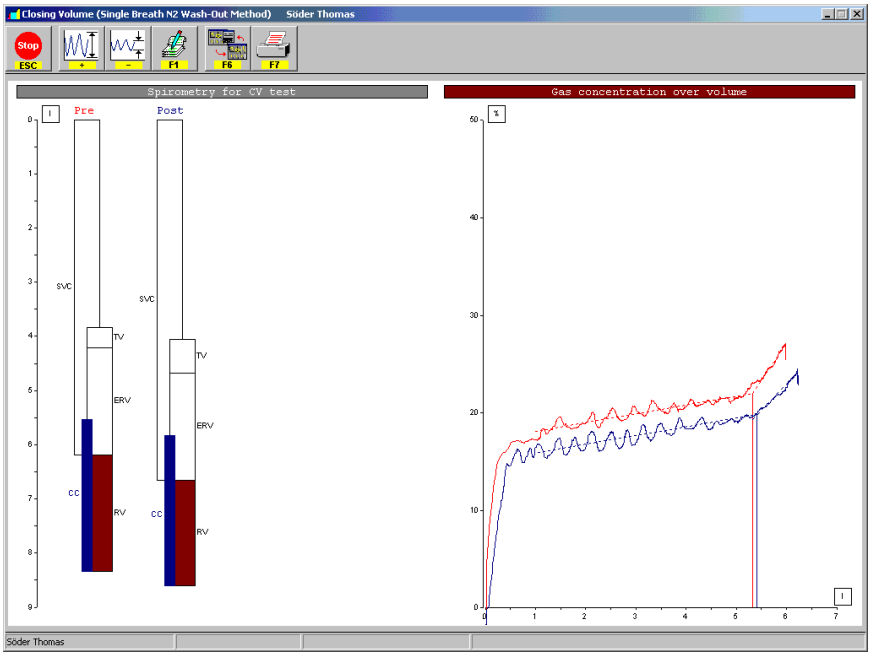
However, all other aspects remain unchanged; in particular, you can continue to determine the areas for phase III and IV and thus the value of CV manually.

4.8.7 The CV program in the display mode (multiple measurement)

You can compare up to five CV measurements!

When displaying several measurements, the operator icon 

will not be shown. The remaining icons are the same as those displayed when viewing a single measurement.



The spirometry volume time graphs have been replaced by bar graphs of the individual measurements. Each bar graph is aligned to TLC.

The inert gas traces and the respective regression lines of the individual measurements are overlayed and the colours will correspond to those in the bar graphs.

The cursors cannot be moved manually.

5 Disinfection and Maintenance

5.1 General Disinfection and Maintenance Recommendations

All parts of the ZAN equipment, which can get contaminated by the patients breath are designed for simple and complete disinfection.

Caution: To avoid infections in connection with medical devices, directly contaminable parts have to be disinfected after each patient.

Important: Disinfection must be carried out at low temperature (140°F or 60°C maximum, e.g. with cold disinfectants, cold gas, or plasma disinfection). If you choose an antiseptic solution, you have to make sure that it does not contain high concentrations of chloride ions and that the material characteristics (of the parts to be disinfected) will not be influenced.

ZAN has tested the following disinfection fluids for their compatibility with the used materials.

Korsolex extra	Bode Chemie
Korsolex plus (Aldehydfree)	Bode Chemie
InstruPlus	Dr. Deppe
EndoStar (Aldehydfree)	Dr. Deppe

for surface disinfection:

Antifect FD10	Schülke & Meier
ST-Tissues	Bode Chemie
SprayIn (Aldehydfree)	Dr. Deppe
(Caution: inflammable at low temperature (25°C))	

Caution: **Always consider the recommendations from the disinfectant manufacturers concerning concentration, purpose, and reaction time.**

Note: Visible dirt must be removed before actual disinfection**..**

- ► Daily use and disinfection of the parts and the flow sensors will influence their mechanical quality.
- ► We strongly advise you to calibrate and maintain the device according to the given recommendations.
- ► Some components of the device are connected with tubes. The tubes must not be put into disinfectants. Water droplets have to be removed from the tube connections before putting the device into operation.
- ► The complete ZAN system has gaskets (O-rings) for connection. The O-rings should be covered with a thin layer of Vaseline (accessories) to make them slide easily.

- The tightness of the connected parts is very important, so the O-rings have to be checked regularly. The O-rings consist of silicone and must only be replaced by ZAN replacement O-rings.
- PolyOxyMethylen (POM), Ultraform H2320 by BASF, is exclusively used as the basic material for all white plastic parts.

In addition to the information provided in this section, you should refer to your local hygiene or infection control board for their guidelines on cleaning the medical equipment and/or accessories described in this manual. Other sources of information on cleaning are the American Association of Respiratory Care AARC[2] and ATS[3] clinical practice guidelines

5.2 General Recommendations For Surface Disinfection

All personal should wear protective clothing when handling contaminated or polluted parts.

Inhalation or direct contamination of the skin with the disinfectants can be dangerous to the health of the personal.

Always consider the recommendations from the disinfectant manufacturers concerning concentration, purpose, and reaction time.

Cleaning tissues should only be slightly moistened with the Disinfectant

Warning: **The ZAN Electronic modules are not protected from liquids that could get inside the unit. Before cleaning the surface, please unplug the device.**

Important: **Make sure that no moisture will get inside the device, because this could lead to short circuits or shock hazards and the contacts might oxidise.**

5.3 Using Filters

Bacterial filters do not only retain saliva, but also micro organisms like viruses, bacteria, dust and other contaminating substances. The use of a filter (disposable, single use) between mouthpiece and flow sensor guaranties optimum security for the patient, concerning infection protection.

Note: **Although the filters are very effective (better then 99%), they can not replace disinfection of the parts of the devices**

Flow sensor and the parts of the shutter, described below, should be disinfected at least once per day, even if filters are used with every patient.

There is no difference in the way parts have to be cleaned and disinfected when filters are in use.

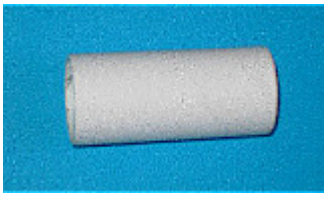
[2] AARC Clinical Practice Guideline – Spirometry, 1996 Update, reprinted from Respiratory Care, Vol 41, No. 7, pp. 629-636, 1996.

[3] American Journal of Respiratory and Critical Care Medicine, Vol 152, No. 6, pp 2188-2189, December 1995.

5.4 Disinfection Of Particular Components

5.4.1 Small Parts And Materials

All parts that may be sterilised, may also be cleaned using a chemotechnical disinfection in an RDG device.

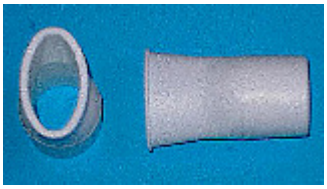


5.4.1.1 Paper Mouthpiece

Cardboard mouthpieces are disposed of after use. They are single patient use.

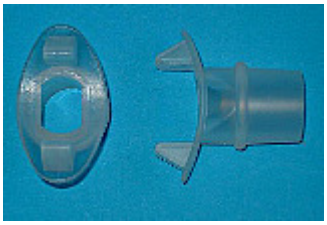
5.4.1.2 Nose clips

Nose clips can be sterilised in 121°C hot steam (autoclave) and ethylenoxid.



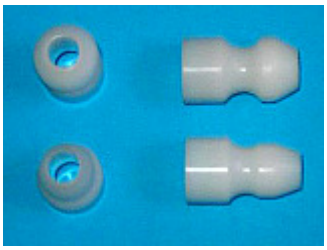
5.4.1.3 Plastic Mouthpiece

Plastic Mouthpieces can be sterilised in 121°C hot steam (autoclave) and ethylenoxid.



5.4.1.4 Bite Mouthpiece

Bite Mouthpieces can be sterilised in 121°C hot steam (autoclave) and ethylenoxid.

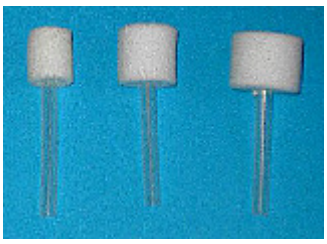


5.4.1.5 Nasal Tips

Nasal tips can be sterilised in 121°C hot steam (autoclave) and ethylenoxid.

5.4.1.6 Nasal Adapter

Nasal adapters can be sterilised in 121°C hot steam (autoclave) and ethylenoxid.



5.4.1.7 KoKo Moe Filter

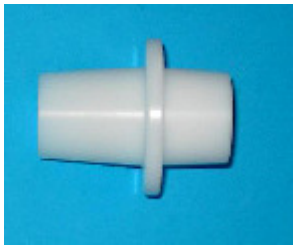
Filters have to be disposed of after use. They are single patient use. For replacement use only ZAN certified filters.

5.4.1.8 Olive Holder

Olive holders can be sterilised in 121°C hot steam (autoclave) and ethylenoxid.

5.4.1.9 Adapter

Adapters can be sterilised in 121°C hot steam (autoclave) and ethylenoxid.



5.4.1.10 Cleaning and Disinfecting the Breathing Mask

Caution:

Breathing mask must be disinfected after every patient. We strongly advice you to follow the instructions of the manufacturer of the mask, which can be found in the original packing.

5.4.2 Disinfecting The Flow Sensor

Caution: The flow sensors can be exposed to a maximum temperature of 140°F or 60°C during disinfection. Higher temperatures could destroy the variable diaphragm on the inside of the tube

To disinfect the flow sensor, the sensor must be removed from the Flowhandy ZAN100 USB body and put into a disinfecting bath.

It is advisable to remove visible dirt before the actual disinfection.

An ultrasound cleaning of the flow sensors should only be carried out when it is necessary because the mechanical quality of the membrane could be influenced.

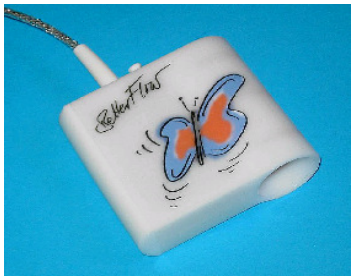
Caution: To avoid infections in connection with the flow sensor, it must be disinfected after each patient.

Always consider the recommendations from the disinfectant manufacturers concerning concentration, purpose, and reaction time.

- ► The inside of the flow sensor must neither be rinsed with a direct jet of water out of the pipe, nor must it be cleaned or touched by mechanical tools. This could damage the sensitive plastic orifice and disturb the correct measuring function.
- ► The flow sensor must be carefully dried after disinfection. Before use you have to make sure that there is no more water in the holes.
- ► If necessary blow out the holes with compressed air.

Hint: Compressed air in sprayers for medical purposes is available from your dealer.

9.1.1 Disinfection Of The Flowhandy



The Flowhandy ZAN100 USB contains electronic components and may never be plunged into liquids. It is possible to use surface disinfection using pieces of cloth etc.

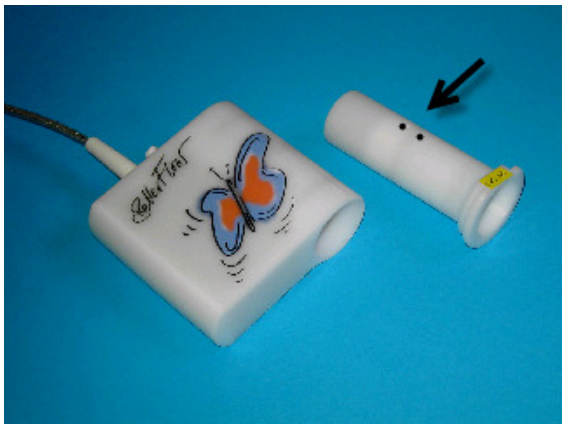
If carefully applied, a spray disinfection is possible.

The white pressure sensor on the rear side of the device must NOT be sprayed directly.

5.4.3 Assembly Of Handy And Flowsensor

Before the Flow sensor is inserted into the Handy again, the O-rings should be covered with a thin layer of Vaseline (accessories) to make them slide easily

Caution: Do not block the holes on the top side of the flowsensor.



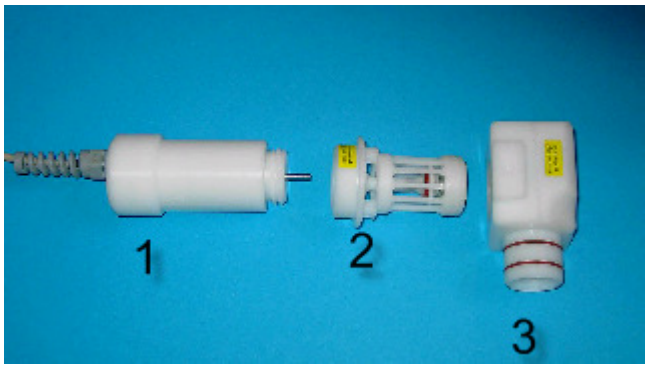
Insert the flow sensor in a way that the holes (and the yellow mark on the front rim) are in top position. This will prevent liquid getting inside the device

5.4.4 Disinfection Of The Shutter

The Shutter can be dismantled in three parts.

1. Shutter engine
2. Shuttervalve
3. Shutterhead

The Shutter Valve and Shutter Head can be plunged into disinfectant liquid. Spray can also be used.



Important: Do NOT put the shutter engine in any liquid

Caution: The shutter head AND the shutter valve must be disinfected after each patient.
Always consider the recommendations from the disinfectant manufacturers concerning concentration, purpose, and reaction time.

5.5 Disinfection Of The One-Way Valve (CO-Diffusion Option Only)

Caution: Do not plunge the One-Way-Valve into any liquid.
Do not dismantle the One Way Valve**.**

The One-Way-Valve can be disinfected using tissues. Spray may also be used.

For disinfection, separate the valve from the unit and spray it carefully. Spray the orifice from the patients side.

Dry carefully and completely in a well ventilated area.

During reassembly, the O-rings (gaskets) should be covered with a thin layer of Vaseline (accessories) to make them slide easily.

Caution: In order to exclude any danger in relation with the shutter, the shutterhead AND the shutter valve must be disinfected after each patient.

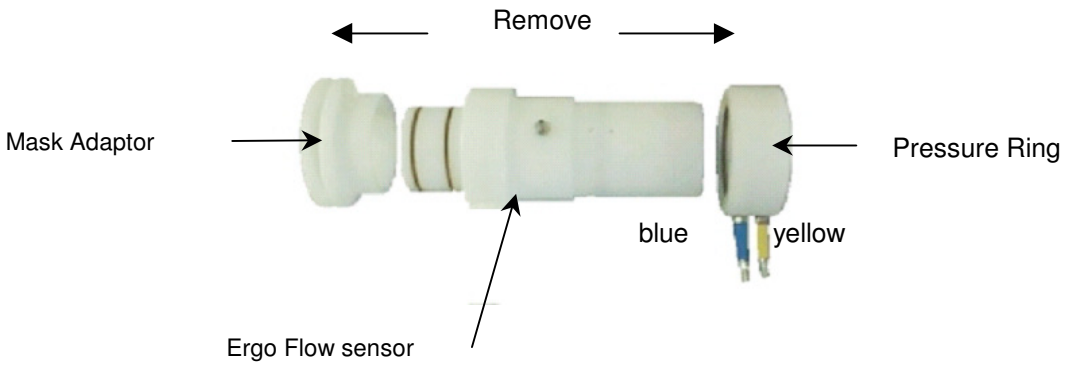
Use of filters is strongly recommended.

Always consider the recommendations from the disinfectant manufacturers concerning concentration, purpose, and reaction time.

5.6 Disinfection of the Ergo Flow Sensor (ZAN 600 / 680 only)

Assembled Ergo Flow Sensor with adapter and mouthpiece

To disinfect the flow sensor, the pressure ring must be removed. It can be pulled off to the back, seen from the patient's point of view. When you put the pressure ring on the flow sensor again, please consider that the blue connection points towards the flow sensor.



Caution: The blue connecting piece on the pressure ring must point towards the patient

The opening of the water trap must be closed again with a new cotton plug

It is recommendable to remove visible dirt before the actual disinfection.

An ultrasound cleaning of the flow sensors should only be carried out when it is necessary, because the mechanical quality of the membrane could be influenced.

Warning: To avoid infections in connection with the flow sensor, it must be disinfected after each patient.

Always consider the recommendations from the disinfectant manufacturers concerning concentration, purpose, and reaction time.

- ► The inside of the flow sensor must neither be rinsed with a direct jet of water out of the pipe, nor must it be cleaned or touched by mechanical tools. This could damage the sensitive plastic orifice and disturb the correct measuring function.
- ► The flow sensor must be carefully dried after disinfection. Before use you have to make sure that there is no more water in the holes.
- ► If necessary blow out the holes with compressed air.

Hint: Compressed air in sprayers for medical purposes is available from your dealer.

Caution: The flow sensors can be exposed to a maximum temperature of 140°F or 60°C during disinfection. Higher temperatures could destroy the variable diaphragm on the inside of the tube

Hint: **The pressure ring does not need to be disinfected.** Only pressure is detected at the orifices of the Flow Sensor and no breath flows into or out of the openings back or forth. Transport of germs and viruses or infection of a patient is impossible through this path.

We recommend cleaning the pressure ring regularly with wipe disinfection. Care must be taken to not block the holes.

The O-rings should be covered with a thin layer of Vaseline (accessories) to make them slide easily.

5.7 Disinfection And Cleaning The Bodychamber ZAN 500

Caution : **There is no protection of the electronics against incoming water or liquids.**

5.7.1 Cleaning The Camber And the Glass Panes

The cabin can be cleaned with ordinary cleansers. Use soft tissues or leather and wipe with hot soapy water.

Make sure the fabric is not wet, but moist and moisture will not get inside the device. If moisture gets inside the device it can cause severe damage to the sensors and electronics.

Do not use aggressive cleansing agents.

5.7.2 Maintaining the Rubber Gasket Of The Door

Never clean the rubber gaskets with aggressive cleansers.

To avoid early ageing of the rubber, it is strongly recommended to at least once per month apply talcum powder to the gasket or use the special rubber maintenance stick, which is available from your dealer.

Visible and cutting cracks of the rubber will influence the seal of the chamber.

Recalibrate the chamber for control and call the ZAN service to replace the rubber gasket if necessary.

5.7.3 Disinfection Of Parts of the Chamber Which Are In Contact With The Patient

Use disinfection tissues or spray for disinfection after each patient. Ventilate properly to avoid irritation to the next patient.

5.8 Cleaning The ZAN Electronic Modules

Warning: The ZAN Electronic modules are not protected from liquids that could get inside the unit. Before cleaning the surface, please unplug the device

The ZAN modules can be cleaned with a piece of cloth that has been moistened in soapy water. Make sure that no moisture will get inside or on the contacts of the device, because this could lead to short circuits or **shock hazards** and the contacts might oxidise.

Permanent electrodes must be cleaned in regular intervals. This is important to ensure good signal quality.

Please refer to the manuals of the manufacturer for detailed information about cleaning and maintenance of the suction device.

5.9 Disinfecting and Cleaning Medical Products of Other Manufacturers

To disinfect medical products, which have not been manufactured by ZAN Messgeräte GmbH (e.g. bicycle ergometer, treadmills, and pulse oxymeter), read the documents accompanying these products.

5.10 Cleaning and Disinfection of Parts in the Environment of the Patient

For all surfaces in the environment of the patients, a regular cleaning and disinfection with wipe disinfection is recommended. This should be performed according to the common rules of hygiene after visible dirt has been removed.

To avoid any risk, protective clothing during cleaning recommended, especially when the patient is thought to be infectious.

5.11 Cleaning The Computer Equipment

Computer and peripherals are usually not built for the use in an aseptic environment.

We recommend covering the keyboard with an appropriate coverage and cleaning it regularly with wipe disinfection. There are similar covers available for the computer mouse.

The advice for cleaning the cases, tubes and cables are the same as for ZAN electronic modules.

6 Troubleshooting

6.1 General Problems

Problem	Possible Causes	Solution
After starting the measurement, no volume line appears.	1 Measurement device is not connected to your PC. 2 A wrong port was selected. • A wrong measurement device was selected.	3 Plug ZAN device into the serial interface. 4 Select port or measurement device in the set-up programme. 5 Disconnect the device from the USB port, wait at least 30 sec. reconnect the device, restart the programme.
After starting, the volume line does not run horizontally, even though the patient is not breathing.	6 The zero point was not set correctly. • Condensation or Vaseline is blocking the holes of the flow sensors..	7 With F12 key or selecting  set the zero point again. 8 The patient must not breathe on the device while the zero point is set. • Change flow sensor and carry out new calibration.
After starting the horizontal line runs, but breathing is not shown.	9 The flow sensor has not correctly been put into the case. 10 The interface of your PC is in the Power Down Mode. 11 The O-rings are defective. • The holes of the flow sensors are blocked with water or Vaseline.	12 Put the flow sensor correctly onto the case, there must be no gap. 13 Deactivate the Power Down Mode of your PC. 14 Replace the O-rings. • Clean the holes of the flow sensor or the holes of the flowhandy.
The volume line is recorded downward with inhalation and recorded upward with exhalation.	• Flow sensor has been put into the handy from the wrong side.	• Take off the flow sensor and put it into the handy from the right side
The volume-time curve drifts upward or downward during respiration.	15 The entered ambient temperature is not right. 16 The patient is not wearing a nose clip. 17 The patient does not seal the mouthpiece tightly enough. • The flow sensor is defective or must be calibrated.	18 Activate the BTPS entry module with <B> and correct the temperature. 19 Use a nose clip. 20 The patient must tightly enclose the mouthpiece or use a different mouthpiece. • Calibrate flow sensor or exchange it

6.2 Body Plethysmograph problems

The door cannot be closed.	1. Door magnets have not been activated yet. 2. The door has been deactivated by pressing the security switch.	1. Activate door magnets by selecting the door symbol. 2. Press the security switch again.
The resistance curves are wide open.	1. The door is not completely closed. 2. The temperature sensor is defective. 3. The patient's mouth or nose is not completely closed.	1. Check door lock, both magnets have to close audibly. 2. Call service. 3. Patient must use nose clip and tightly enclose the mouthpiece.
The resistance curves run vertically..	The cabin pressure is not registered.	1. Check cabin door. 2. Pressure transducer is defective. 3. Repeat cabin calibration.
The resistance curves run horizontally.	The respiratory flow is not registered.	1. The flow sensor or the holes of the handy are blocked. 2. The flow sensor has not been put far enough into the handy. 3. The handy is defective.
The TGV curves run vertically.	The cabin pressure is not registered.	1. Check cabin door 2. Pressure transducer is defective.
The TGV curves run horizontally.	The mouth pressure is not registered.	The pressure transducer for the determination of the mouth pressure is defective.
The TGV curves have an oval form..	1. The cabin is not completely air tight. 2. The interruption valve is not sufficiently tight. 3. The mouth does not sufficiently enclose the mouthpiece.	1. Check tightness of the cabin door. 2. Check tightness of the interruption valve. 3. The patient must use a nose clip and tightly enclose the mouthpiece.
Only very small TGV curves appear, but the resistance curves are normal.	Poor co-operation.	The patient must breathe more heavily against the shutter

6.3 Diffusion Problems

During test gas inhalation, the air supply is blocked, the patient cannot inhale.	The pressure regulator of the test gas cylinder is not open and/or the pressure connection is not engaged properly to the test gas cylinder.	Open the valve of the pressure regulator. The pressure connection of the breathing valve has to be put in order to make it engage for a second time. This requires much physical effort.
During test gas inhalation, the air supply is blocked, the patient cannot inhale.	Check gas tube, check if the pump runs, check gas analysers	Connect the tube, start the programme again, check the voltage supply of the analysers
The black inert gas line reacts during the tidal breathing.	The patient has consumed alcohol before the measurement or there is some gas left in his lungs from a previous measurement.	Re- schedule measurement.
During test gas inhalation, the black and red gas signal curves do not increase.	Check gas tube, check if the pump runs, check gas analysers	Connect the tube, start the programme again, check the voltage supply of the analysers.
Volume, CH4- and CO gas lines do not start at the same height.	When the zero point was set, there was some gas left in the tube system.	Set zero point , meanwhile the patient must not breathe on the system.
The gas concentration lines heavily decrease while the patient holds his/her breath.	1. The valve system is not tight. 2. The patient breathes heavily against the valve. 3. The connector on the shutter is loose,	1. Check valve system or exchange it. 2. Ask the patient to hold his/her breath and not to breathe against the valve. 3. Tighten the connector on the shutter, but not too tight

6.4 Ergometer Problems

Ergometer or treadmill does not work	1. Devices are not activated or activated after the programme has been started 2. Wrong mode/protocol selected (Note: Bicycle and treadmill are controlled separately) 3. Maybe another user changed the particular ergometer setting on the ZAN PC	1. Activate device and restart programme 2. Select the correct mode / protocol and restart the ergometry programme 3. Set the settings back to the correct values. (Note: there are example settings for Ergoline and Elmed in the addendum. For other types refer to the appropriate manuals in the "PC control" section)
Treadmill does not react	Caution: The patient must leave the treadmill immediately to avoid accidents! Emergency Stop Function is activated.	Reset emergency Stop function. Restart the treadmill If necessary disconnect the device from the PC, restart the system and reconnect the Ergometer.

6.5 Spiro-Ergometry Problems

No volume signal appears while the patient is already breathing.	1. ZAN600 control light is off 2. Flow sensor is not connected	1. Check power cable and switch ZAN 600 on with the switch on the backside 2. Check connection tubes
No O_2/CO_2 gas signal	1. Analysers are not yet ready (**Note : The analysers need at least 20 minutes to heat up.** Heating time starts with the start-up of the measurement devices) 2. Gas suction tube is not connected to the flow sensor or is interrupted. 3. Wrong gas-calibration or calibration gas cylinder is empty	1. Wait until the analysers are ready 2. Check all tubing's 3. calibrate correctly with a refilled calibration gas cylinder.

Note: To ensure valid measurements, take always care for the following facts

- Always keep volume and gas sensors calibrated to the optimum
- Take care of cleanliness and correct assembly of the sensors
- Watch for tight fit of mask and mouthpiece

7 Software Installation

7.1 Installation

When the system is set up for the first time, install the software and drivers prior to connecting the hardware to the system.

When the software is ready installed, connect the USB plug of your device to a free USB port of your PC system. The device will be recognised by your PC automatically and the appropriate driver will be installed.

Note: If the PC fails to recognise the device: remove the USB plug from the USB port of the PC and wait 30 seconds, then connect again. If necessary, reboot your PC and connect the cable after the reboot . After that, install the ZAN software GP3.xx .as explained below.

7.2 Installation of the ZAN GPI 3.xx Software

Insert the ZAN-CD into your CD ROM drive and the programme starts automatically. Follow the prompts to install the software. If the installation does not start, use Windows Explorer to locate the set-up file (setup.exe) on your CD-ROM and start it manually.

A window pops up. Select the language of the installation and the ZAN Software and confirm by pressing [OK]. Available languages are: English, German, French and Spanish.

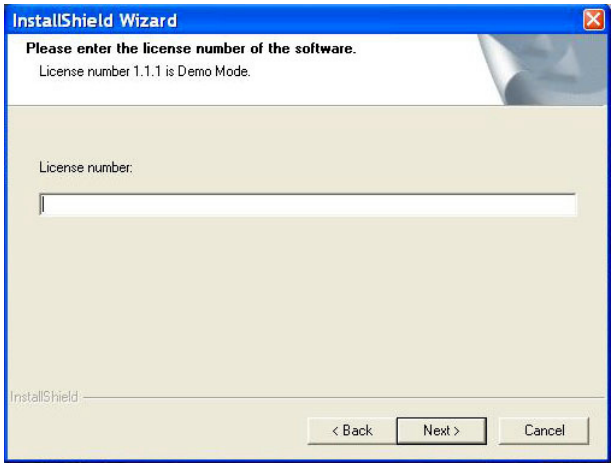
The Install Shield Wizard will be prepared...

...and opened. Click [Continue].

If you agree with the license agreement click [OK].

Enter the license number that came with your system and click on [Continue].

If you have the measuring device for demonstration only, you can use the programme in the DEMO mode for 30 days. To use the DEMO mode, enter the license number 1.1.1.

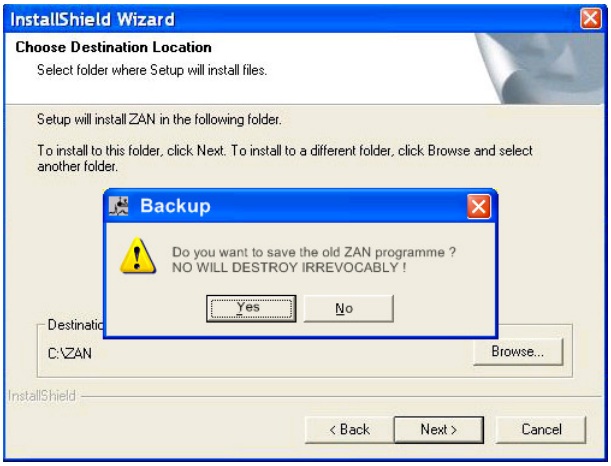


The standard installation directory is C:\ZAN

Caution: **Do not change the destination folder. This may cause problems with the software. Contact nSpire Health or your local dealer if you have any questions. If you change the destination folder, nSpire Health cannot be held responsible for possible problems.**

If you have selected a directory that contains an older ZAN version, the set-up will suggest you make a backup. Clicking on [Yes] will store the older ZAN installation at C:\ZANOLD\ZAN,<Date>,<Time>.

Clicking on **[No]** will permanently delete the older ZAN installation as well as the archive, and the new version will be installed.



If you have an Internet Explorer Version that is older than the version 6.0, you are prompted to update. It is recommended to install Internet Explorer 6.0 or a newer version.

Only in DEMO-MODE!

If you are installing the DEMO software, select the ZAN Option (measuring device) you want to install.

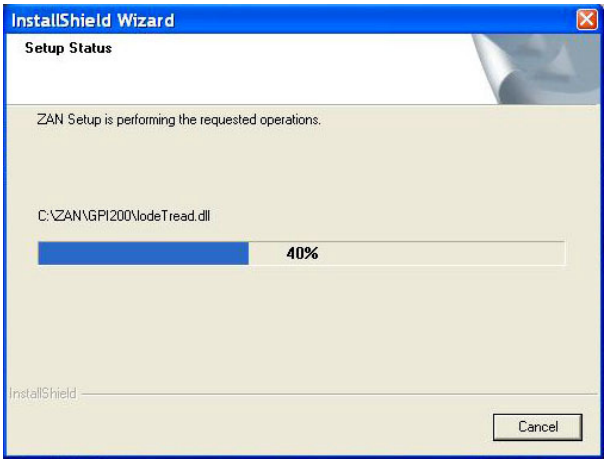
Caution: If you selected a main device, all options will also be chosen. Therefore, also click on the + symbol on the left, next to the relevant option.

Only in DEMO-MODE!

If you are installing the DEMO software, select the + symbol in front of the option. The check mark indicates your choice. If you have selected all measuring devices and options you have purchased, click on [Next].

Check the set-ups before installation and click on [Next]. If necessary, click on [Back] and change the set-ups.

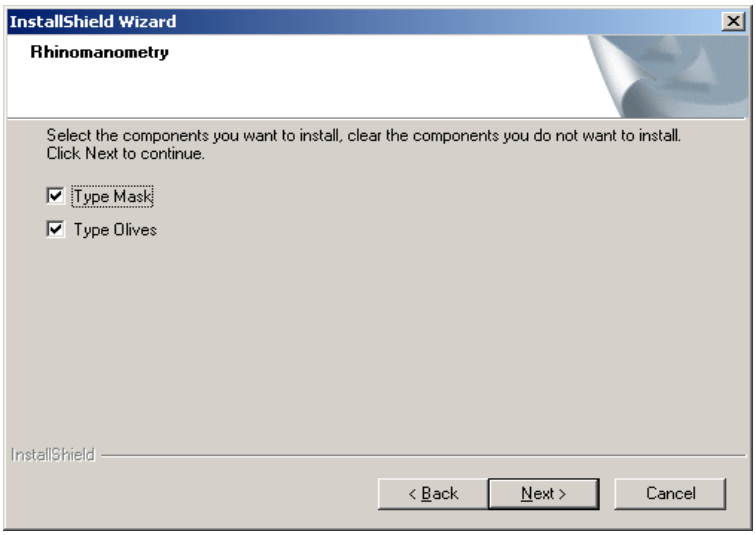
The ZAN programme will be installed automatically.



Only with Option RHINOMANOMETRY!

During the install you will be asked if the Rhinomanometry will be performed with olives or with a mask. Check the appropriate box and press [NEXT].

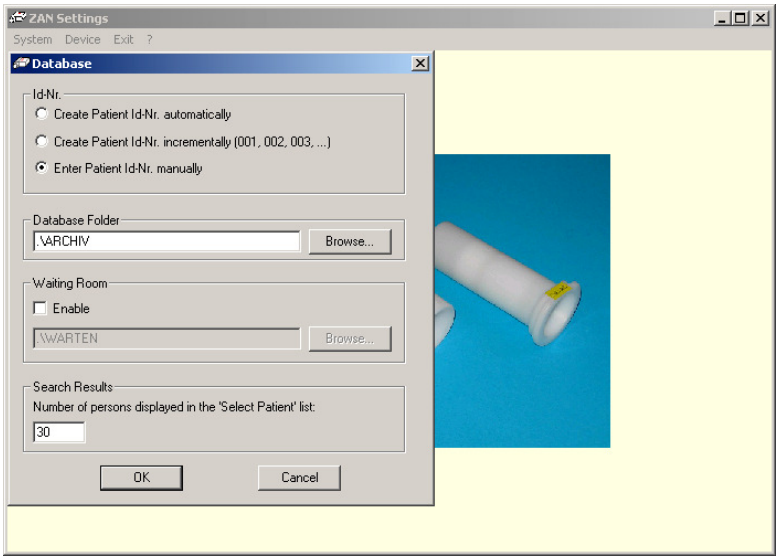
The Installation continues.



Only with ZAN600 and Option ECG!

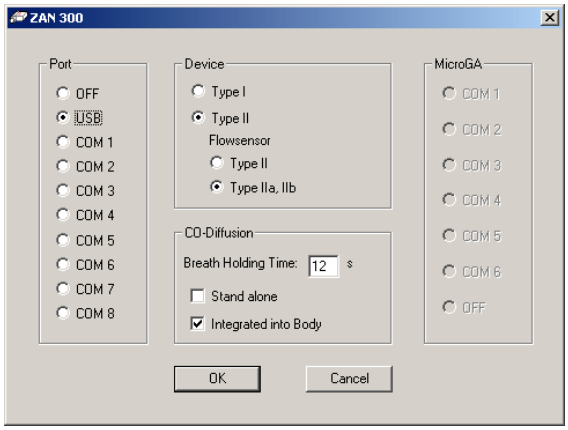
In case the ECG option has been purchased, at this time the installation process branches to the Spacelabs Cardio direct installation. Please refer to the original manual for detailed information about the installation procedure.

Next dialog in the standard installation procedure is the database dialogue.

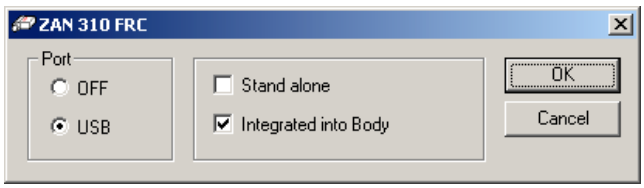


After finishing the database dialogue, several device settings dialogues pop up, depending on your license. All settings made here can be changed during normal operation using the Set Up option in the main menu.

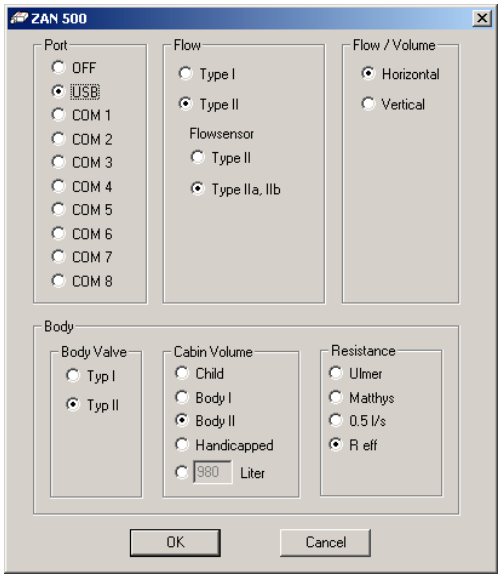
ZAN300



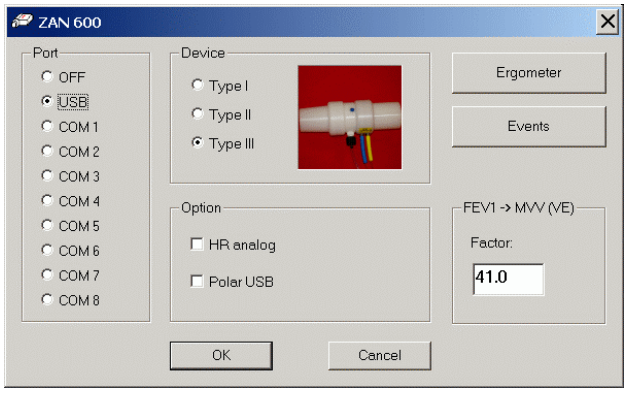
ZAN310



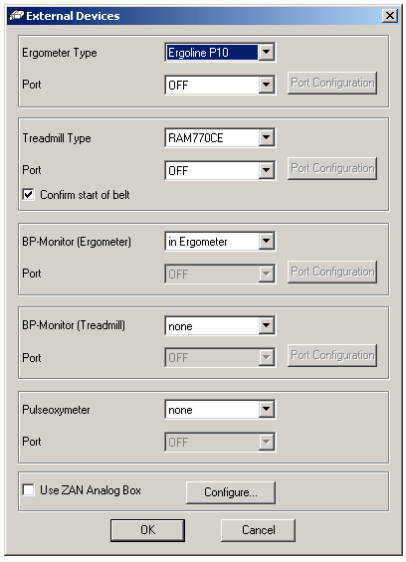
ZAN500



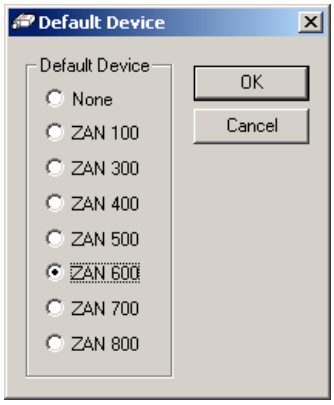
ZAN600



External Devices



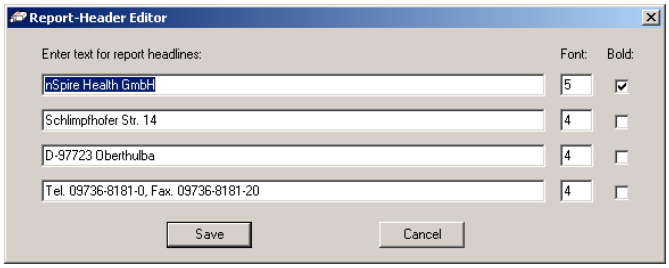
Set the default device



After the Installation the Protocol-Header-Editor pops up.

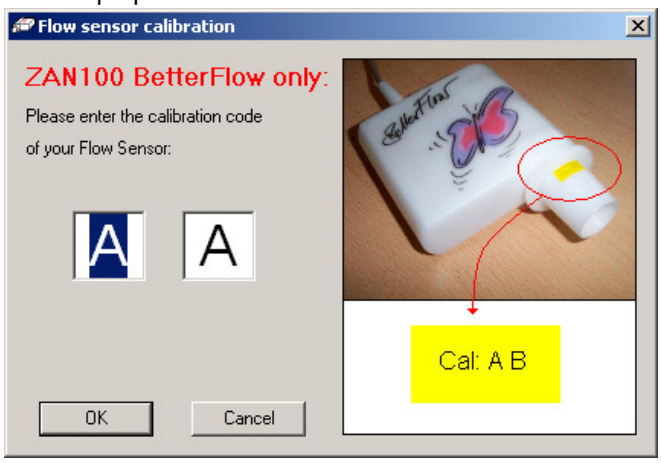
Enter your practice or clinic data as desired.

To store these data, click on <Save>.



Note:
These data can be changed at any time using the Set-up option.

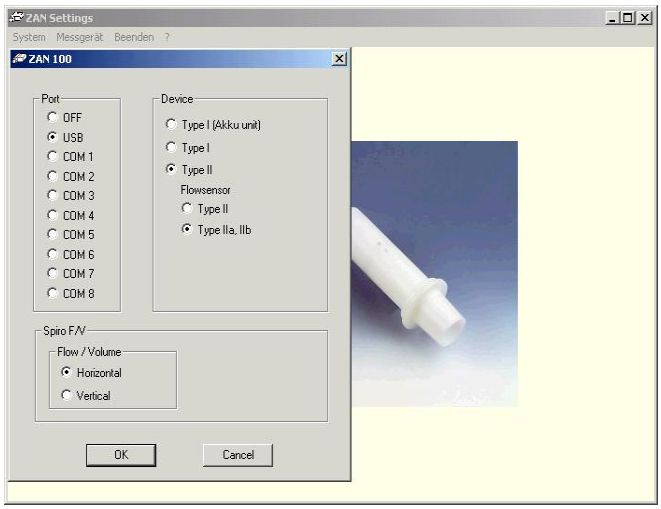
Next you will be prompted to enter the CAL Code of the mounted flow sensor. You find the cal-code on a sticker on top of the frontal rim of the sensor. You find a two character code. Enter the two characters and press [OK]



Note:

The Cal code must be checked on every change of the flow sensor! Change the settings using the option "Calibration" and the ch apter Volume calibration.

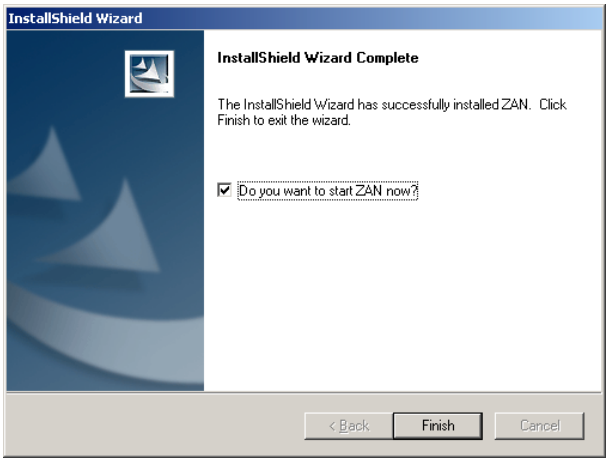
If not already done, you are prompted to connect the devices to the PC and press [OK]



When the ZAN-Settings window pops up, you can configure settings of the several device interfaces and other important settings like printer type, report headlines, database settings etc.

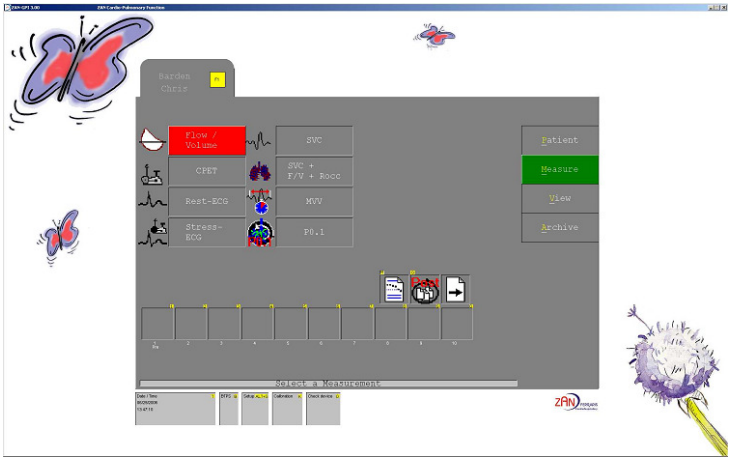
You can change all settings at any time using the S option from the main window.

The active device is displayed in the upper left corner. All settings relate to this device only and may vary from device to device.

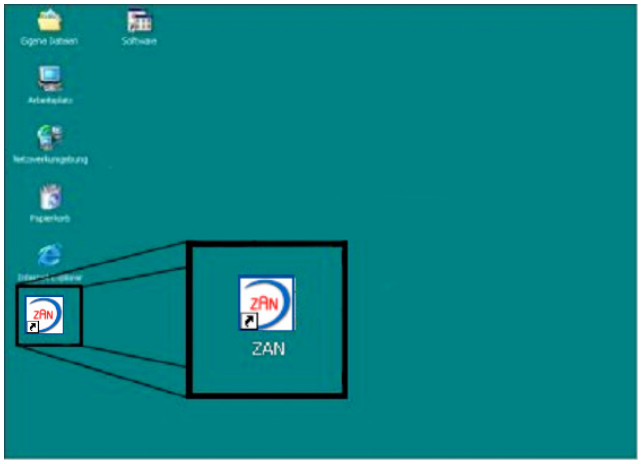


The installation is complete. Click on [**Finish**] in order to close the Install Shield Wizard.

The installation is complete and the software is ready for operation.

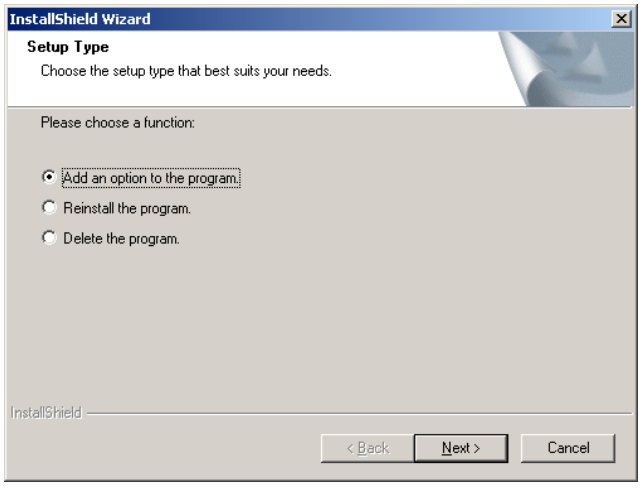


Start the ZAN programme by double clicking on the ZAN icon. Before the first measurement and after the replacement of a flow sensor, it is recommended to perform a calibration.



7.3 Modifying, Reinstalling, or Deleting the Software

To modify, update, or delete the programme, insert the installation CD. The screen to add options to the programme or to completely delete the program is displayed.



Note: Select "**Modify the Programme**" to add new components.

„**Reinstall**" is only able to repair existing, install updates or perform a new installation.

Select "**Delete**" to delete the ZAN programme and all related data.

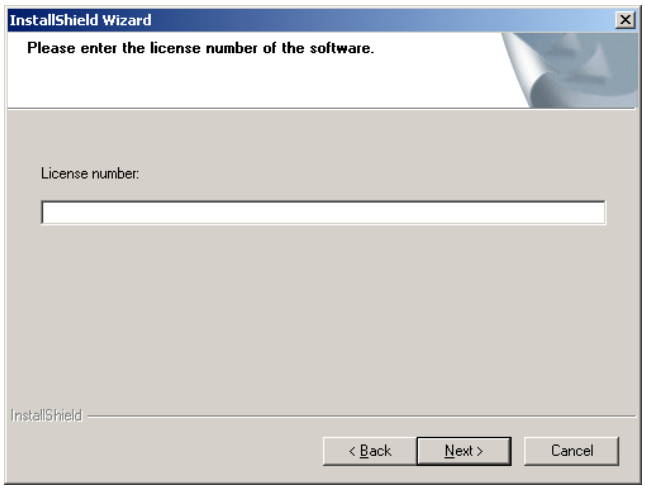
Demo Mode Only

If you chose "Modify the Programme", you will see this window. Now you can install additional options. This programme behaves just like the normal installation programme. Just follow the prompts.

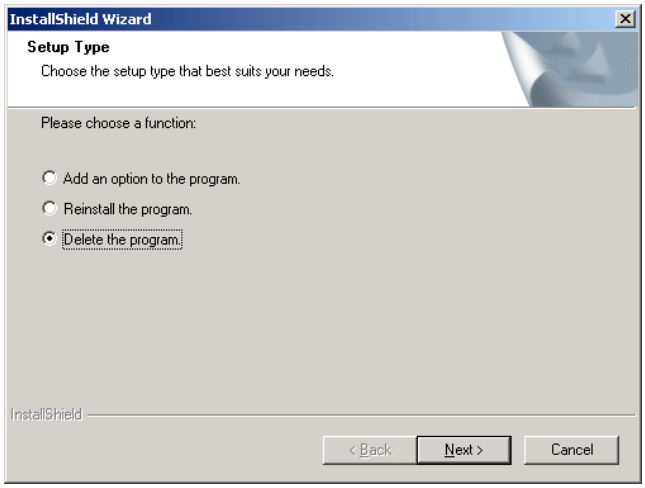
If you choose "Reinstall" you have to enter your new or existing license number. After confirming the rest of the process works automatically.

It is similar to an installation and does not need major changes.

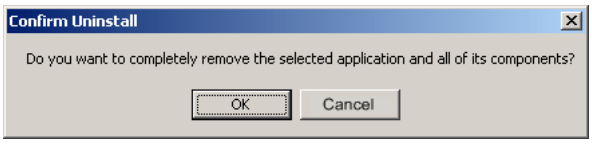
Note: You should use the "reinstall" option only to repair, update or reinstall.



If you select „Delete“, you are prompted to confirm that you are really sure, that you want to delete all programmes and data from your computer.

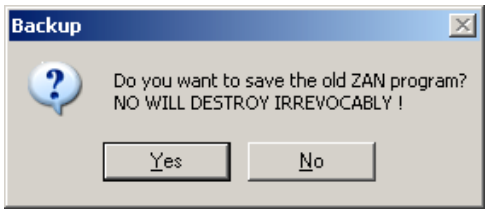


If you want to do so, click on [OK], if you are not sure, click on [Cancel]



If you clicked on [OK], you are prompted to create a backup before deleting. We strongly recommend creating the backup!

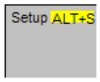
If you choose [No] all data related to the ZAN programme, including your settings and the existing patient archive will be deleted! This action is irreversible.



The Deinstall is finished now.

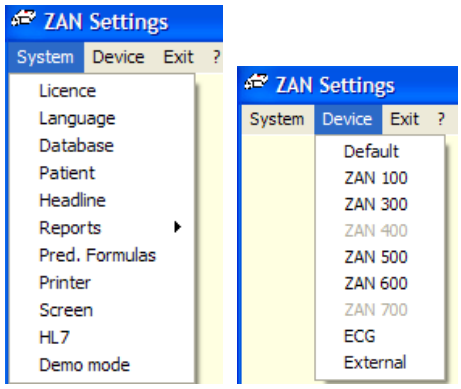
8 Set-up (Customising The Set-up)

8.1 System Set-up

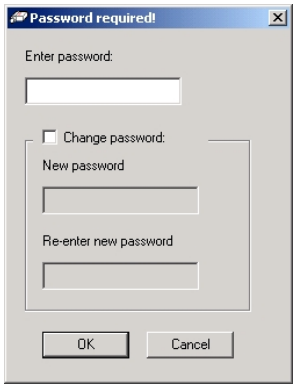
The Set-up Option can be accessed by selecting the 

icon on the lower portion of the screen.

The Set-up Option enables you to set and change some of the programme settings including the following:



Some parameters are protected with a password. if you try to access or edit such parameters, you will be asked to enter your password with the following dialogue box:



Enter the correct password and click on the [OK] button.

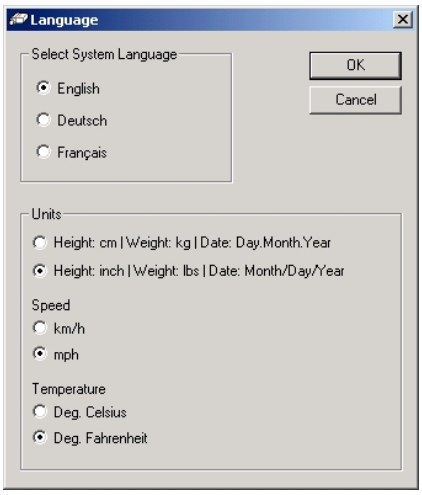
The factory setting for the password is 'Lufu' (entered without the '). The entry is case sensitive.

Click on the 'Change Password' check box to change the password. To avoid typing errors, the password must be entered twice. The new password is active after you leave the dialogue box by

clicking the [OK] button. If you want to discard the changes and stay with the old password, leave the dialogue box by pressing the [Cancel] button.

8.1.1 Language

To activate German, English, French or Spanish language settings.

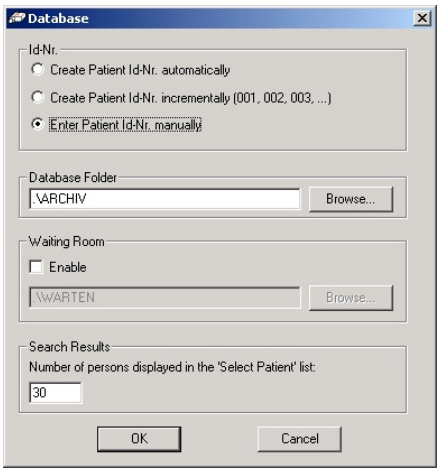


8.1.2 Database

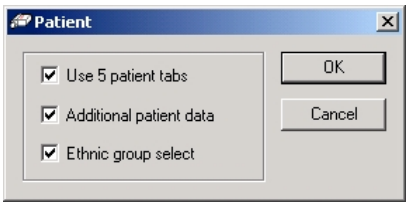
In paragraph 'Id-No.', the format of the patients ID is determined.

In the paragraph 'Database', the user can define the folder, were the patient-archive has to be stored.

Paragraph 'Search Results' defines the number of patients, displayed in the main window as a result of the 'Search Patient' request.

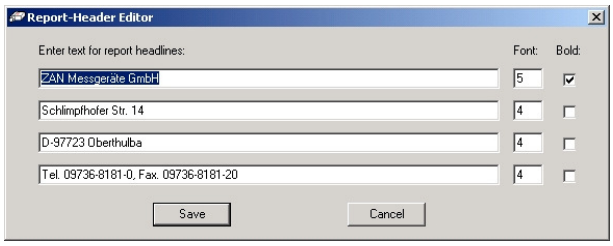


8.1.3 Patient



This turns on multiple tabs in the main window and activates entry of additional patient data and ethnic group.

8.1.4 Headlines



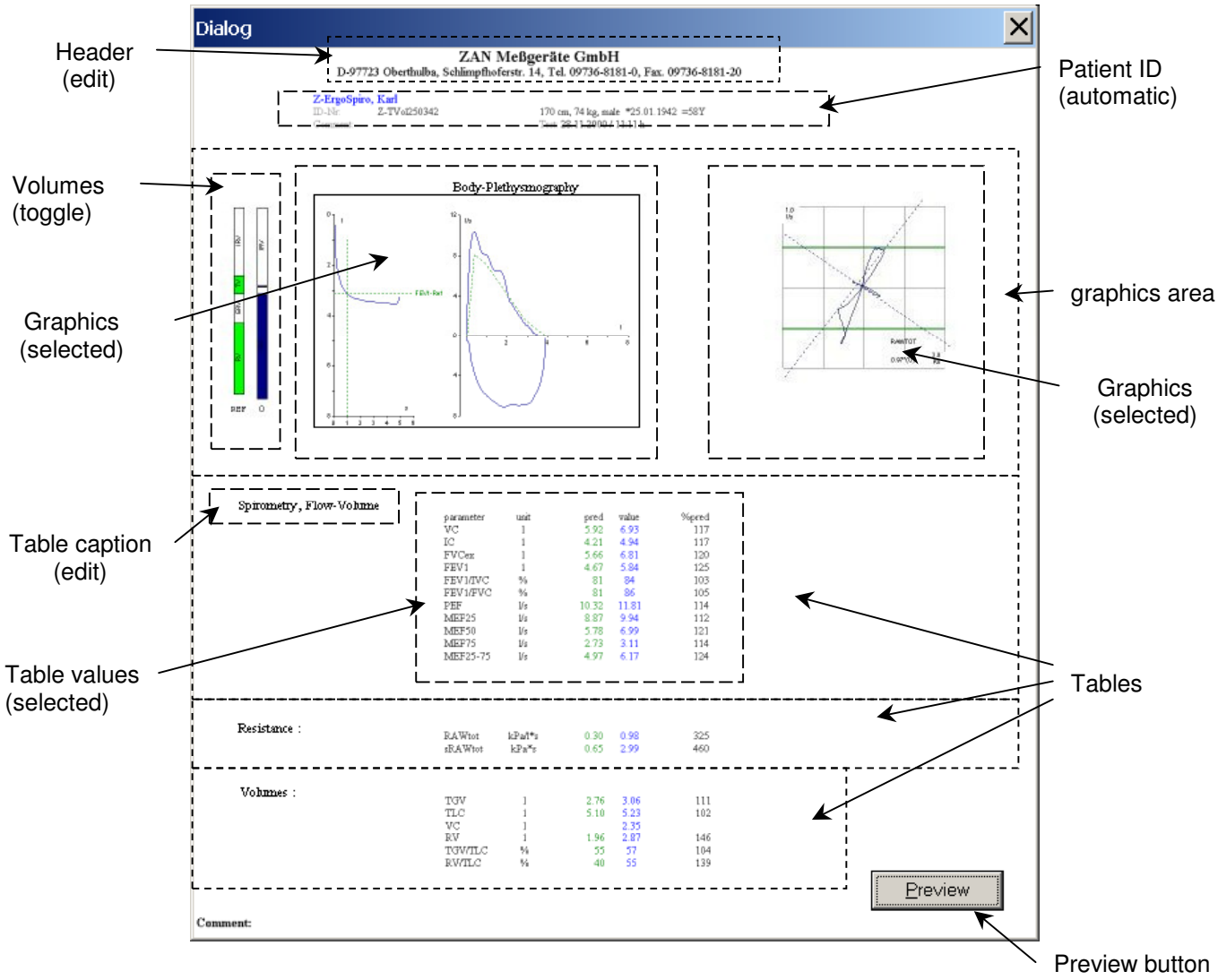
This dialogue box will change the headlines on the printout of the reports.

8.1.5 Report Designer

The ZAN GPI software provides many preconfigured printout forms, which match the most common formats. But in some situations there might be a need to adapt the existing templates to particular demands. In order to give the customer some control over the printed output of the program, nSpire Health provides a simple but sophisticated tool to revise the layout of the print templates.

8.1.5.1 Overview

Every report is derived from the same basic template. This template can be looked at as one side of a printer page. The page is divided into areas. Every area represents a particular element and provides specific editing features. For example: there are text areas which can be edited, other areas contain graphics in which styles can be selected from a menu.



Some areas can be switched off or on (toggled) while others are automatically filled with corresponding data etc..

To activate the editing functionality of an area move the mouse cursor over the desired region until the cursor shape changes to the 'hand' symbol and press the left mouse button. The editor recognises the area the cursor is in and opens the corresponding dialogue, editor or menu.

After modification, the result can be viewed using the 'Preview' button. This opens the MS Internet Explorer window showing the new content of this template.

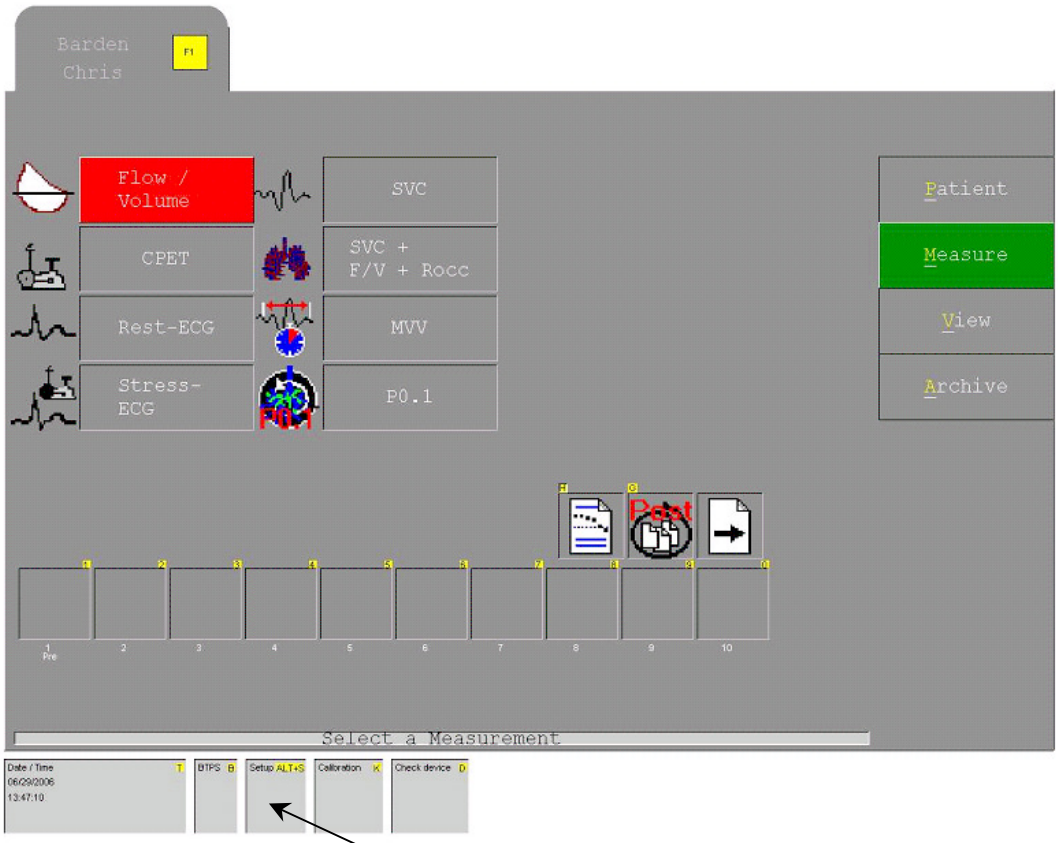
Note: The changes are not visible in the designer window. The designer window acts like a big graphical menu and is designed just to select items to be edited or modified. To see how the editing impacts the layout, you need to use the preview button.

Note: Please select the appropriate font size in you MS Internet Explorer.

To close the designer window, use the 'Close' icon  in the upper right corner. A verification dialogue will pop up to ask you if the changes should be stored permanently or not. This dialogue will only appear if changes have been made to the template.

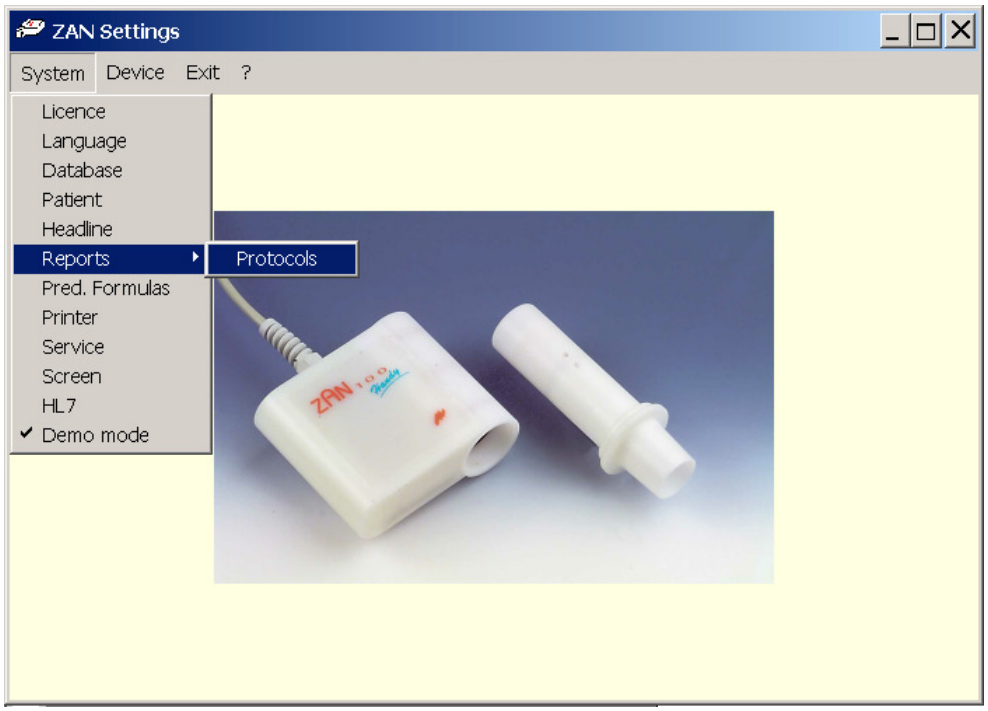
8.1.5.2 Invoking the Report Designer,

From the main menu select Set-up by either pressing ALT +S or clicking the button with the mouse.



Select the Set-up with ALT-S or a mouse click

This opens the 'Set-up' window. From the menu select the drop down list 'System'. In this list you find the item 'Reports'. Move the mouse cursor over the 'Reports' entry and the 'Protocols' subitem pops up. Click on 'Protocols' to invoke the 'Report Selection' dialogue.



Set-up window with open drop down menu

8.1.5.3 Report Selection Dialogue

This dialogue has two different functions:

1. Select a report for editing
2. Organise the print options reports list

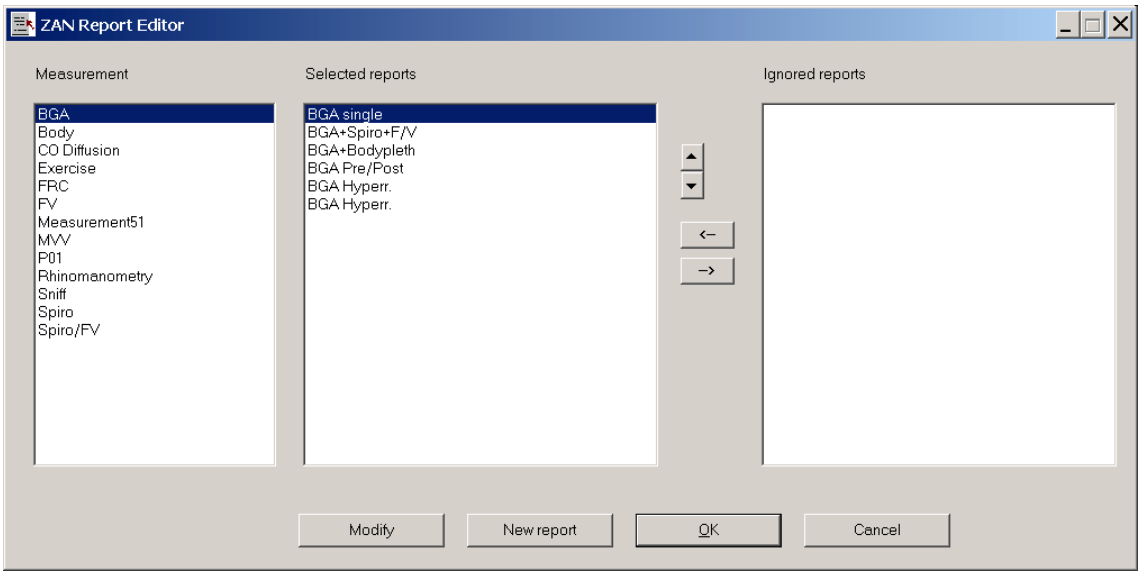
Three listboxes are in the dialogue window.

1. Measurement
2. Selected reports
3. Ignored reports

In the leftmost listbox, all installed measurement methods are displayed. If you select one of the measurements, the corresponding list of installed reports for this method is displayed. The list can be divided in an active part (selected reports) and a passive part (ignored reports). Only active reports are displayed in the print options and can be selected during the measurement.

Use the arrow keys to move a report from the selected to the ignored list and vice versa, as well as to move a particular report to another vertical position in the selected list. In the print selection, the reports appear in exactly this order, so it is possible to move more reports used most often into top positions for easier handling.

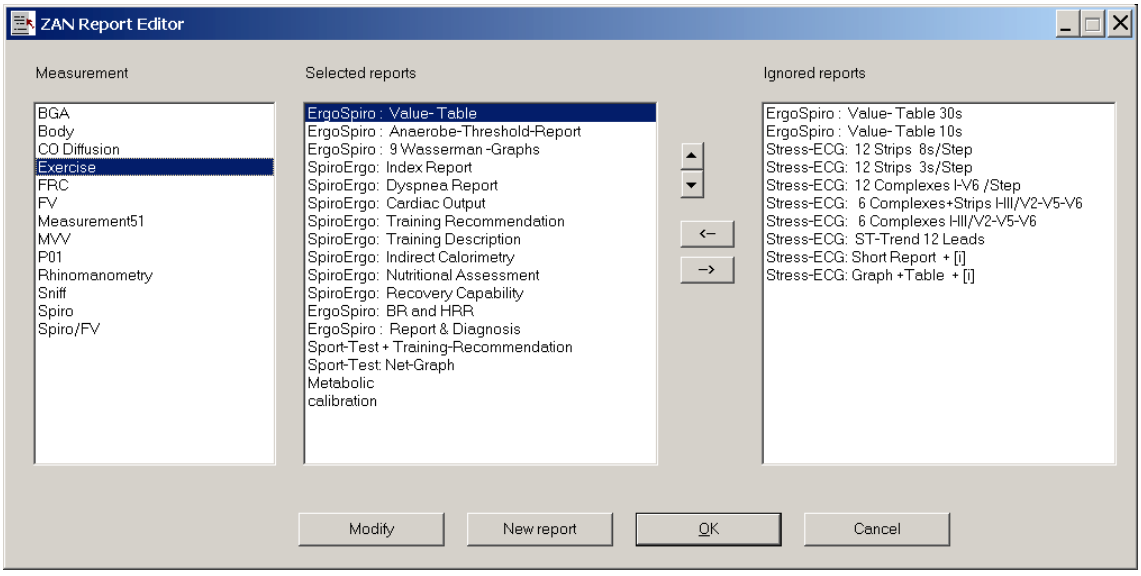
No report template will be deleted. They only remain disabled in the 'ignored' list until they are needed.



Report organiser and selection dialogue

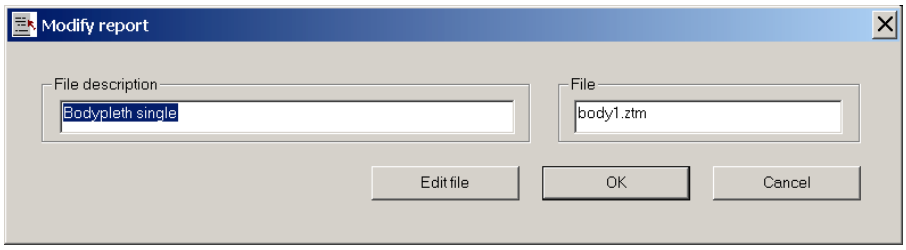
Selecting a report requires three steps:

1. Select the desired measurement method in the leftmost listbox (The list of available reports is displayed)
2. Select the desired report from the 'Selected reports' listbox.
3. Press the [Modify] button to enter the 'Report Designer'



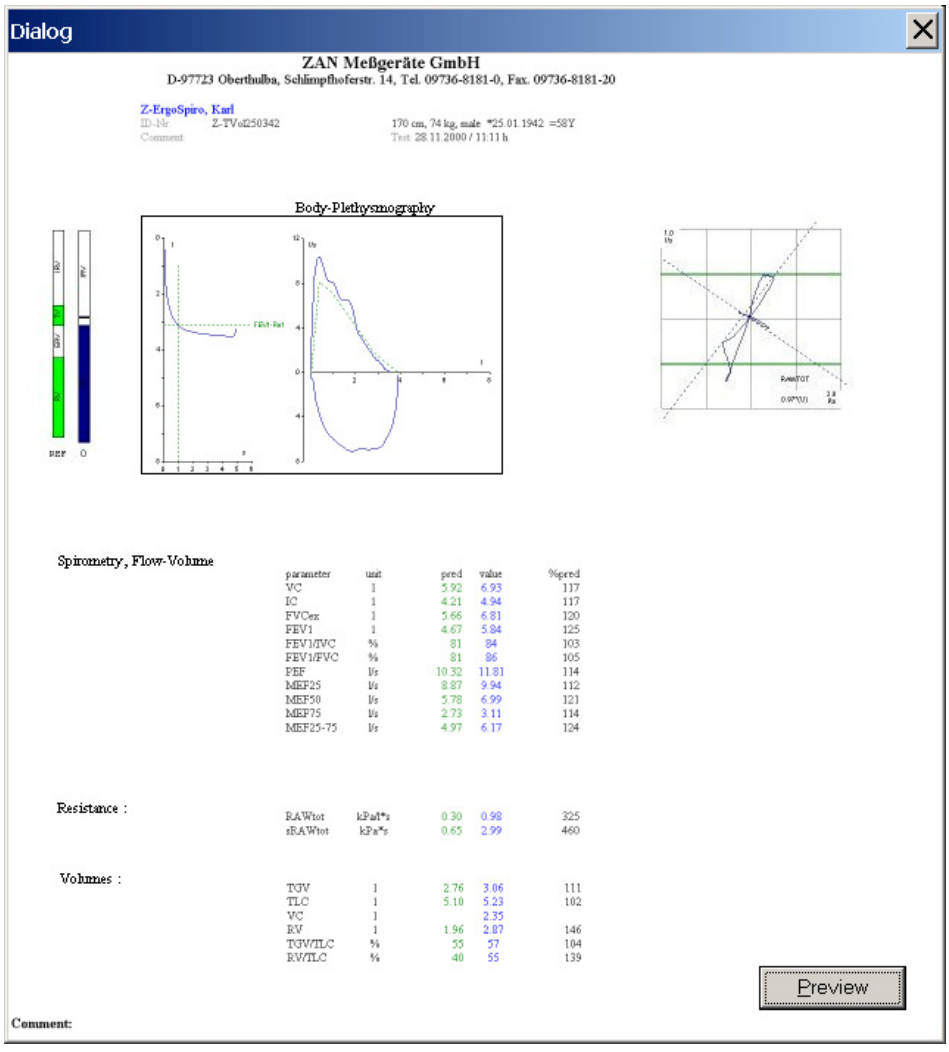
8.1.5.4 Editing the Report

The first option is to change the description of the report, displayed in the listbox and the print selections.



Press **[OK]** to save the changes made in the File Description text box or [Cancel] to abort the process.

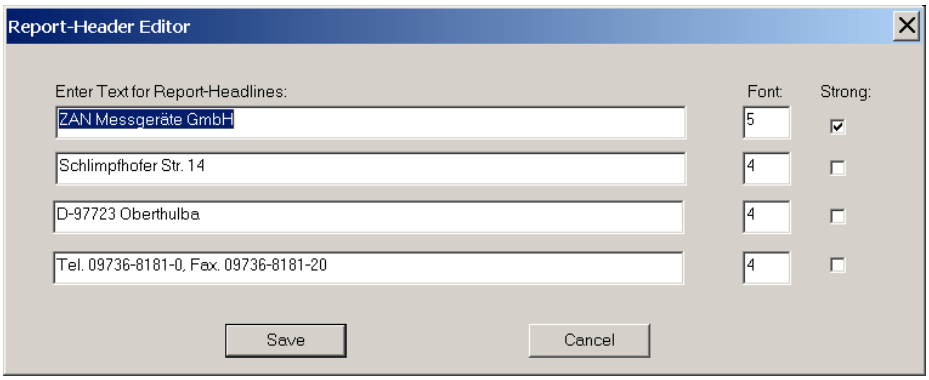
The **[Edit file]** button can be used to enter a basic file editor to review the internal template file. The Report Designer Window appears on the screen.



Report Layout Template

8.1.5.5 Modifying the Header

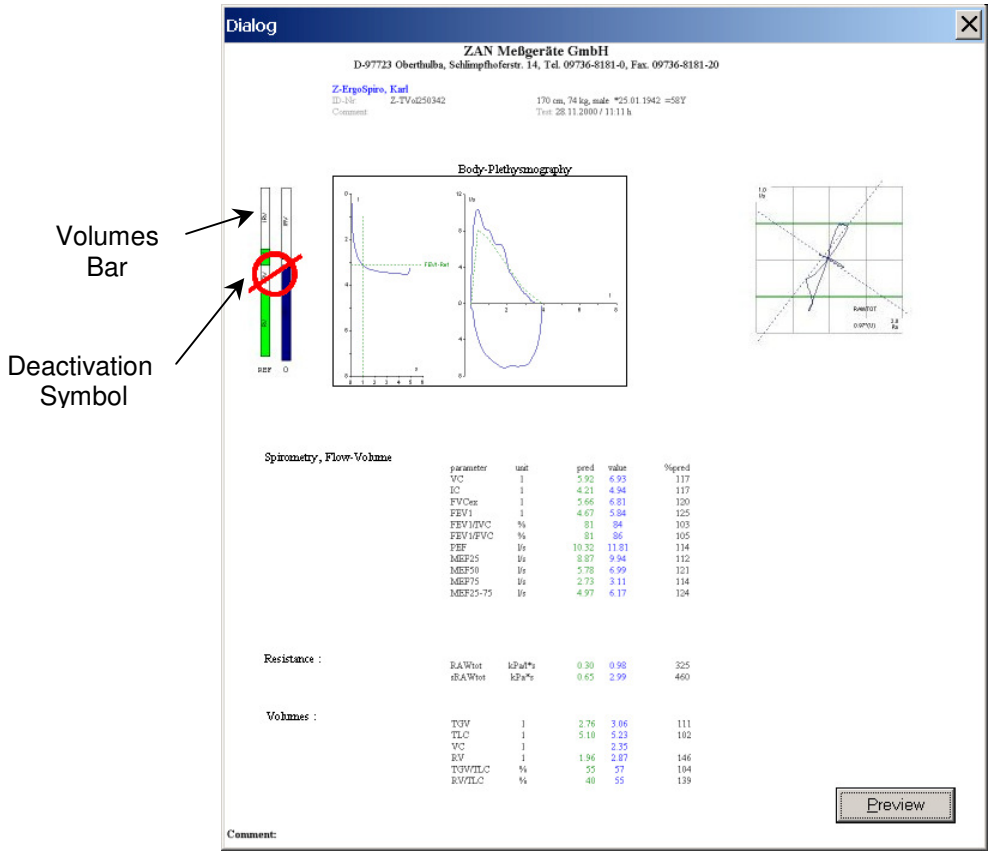
To edit the Header, use the mouse pointer to click into the header area. A dialogue pops up which allows you to change the particular lines in the header



Note: Since there is only one global header definition file in the system, this will change ALL headers on ALL printouts.

8.1.5.6 Switching the Volumes Bar

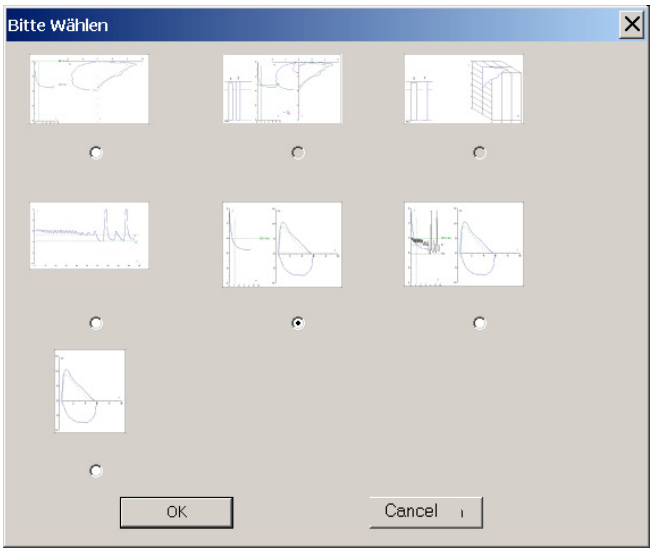
The Volumes Bar is the leftmost graphic element in the graphics area. By clicking on it, it can become activated or deactivated, which means, that it will or will not be printed on this report. If the Volumes Bar is deactivated, the red symbol is displayed over the graphic, like shown below. Otherwise the element is active.



Volumes Bar deactivated

8.1.5.7 Selecting a Measurements Graphic Type

Clicking on the mid part of the graphics area opens the corresponding list of available graphic types.



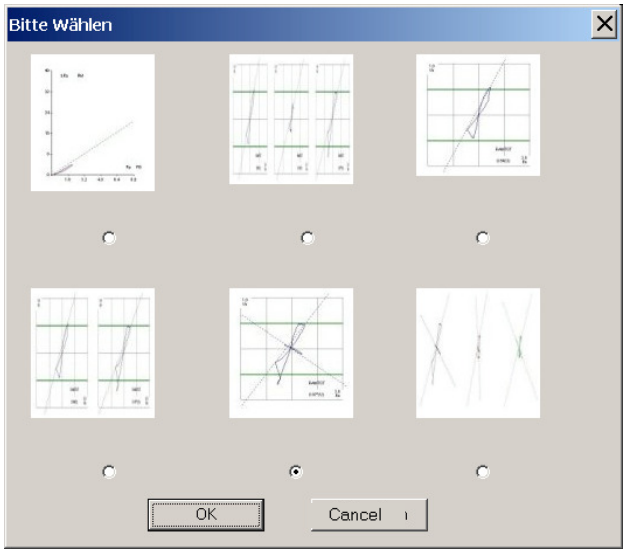
Available graphic types.

In some cases, not all possible graphic types are valid for the selected report. Those graphic types can not be selected and the corresponding radio button fields are disabled (greyed). Only one graphic type can be selected.

Press **[OK]** to activate the selection or [Cancel] to abandon the selection.

8.1.5.8 Select a Results Graphic Type

Clicking on the right graphic element opens the results graphic types selection. The behaviour is the same as in the measurement graphics.

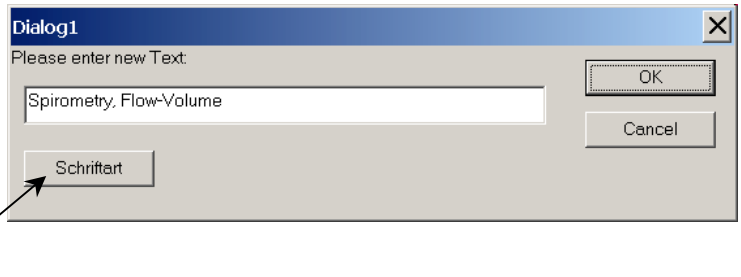


Available graphic types

8.1.5.9 Editing a Table

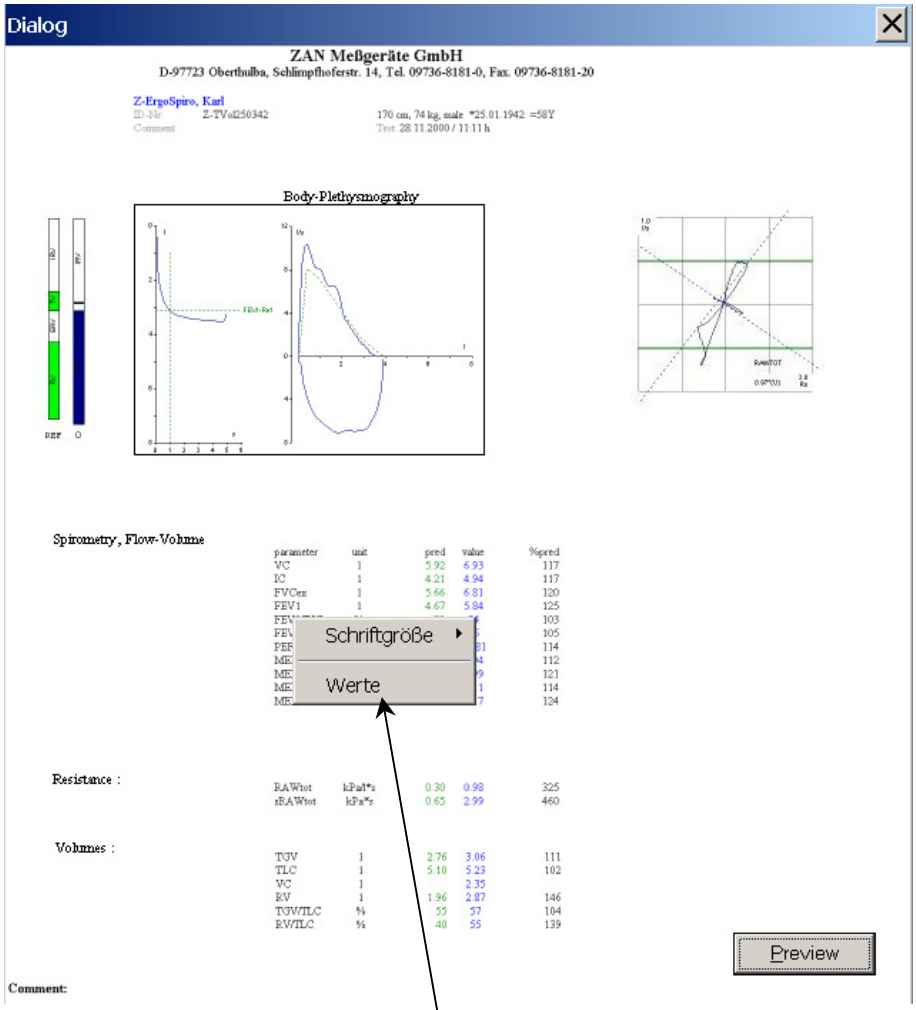
Below the graphics area, the tables area begins. A table is divided into a caption and the table itself. The caption is displayed on the left of the table body.

To edit a caption of a table, click on the requested caption and the edit dialogue pops up.



Use the **[Schriftart]** button to select a font.

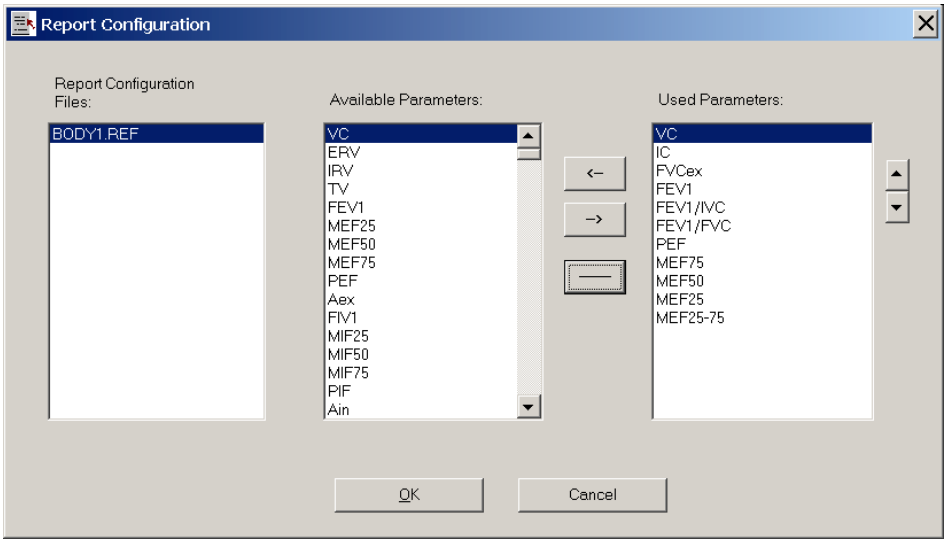
Use **[OK]** to activate the changes or [Cancel] to leave the content unchanged.



When you click into the table, the system offers two options in a pop up menu:

1 **[Schriftgröße]** : means font size, to select a different font size for the table contents

2 **[Werte]:** means parameters, to select a subset of parameters from a menu of available parameters, to be displayed.



Selection of values to be displayed in the table

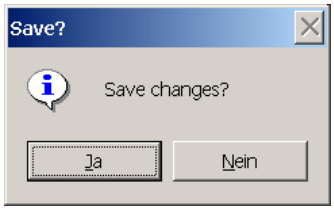
Use the arrow keys to move a particular item from the 'Available' to the 'Used' list and vice versa. Use the arrow keys on the right most side to move an item to the desired vertical order. Pressing the  button inserts a separator at the cursor position to improve readability of the table. Like the parameters, the separator can be selected and moved vertically. To remove a separator, simply select it with the cursor and use the left arrow button  .

After all changes have been applied, use the [OK] button to activate the changes. Pressing the [Cancel] button will discard all changes.

The dialogue will be closed and the user returns to the overview window.

8.1.5.10 Saving the Changes

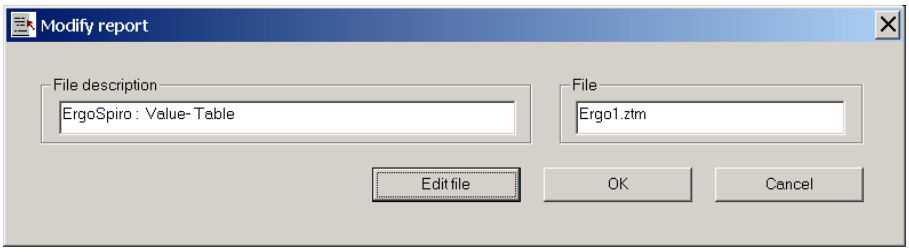
Whenever changes have been made to a template, a verification dialogue pops up, when the user attempts to close the overview window.



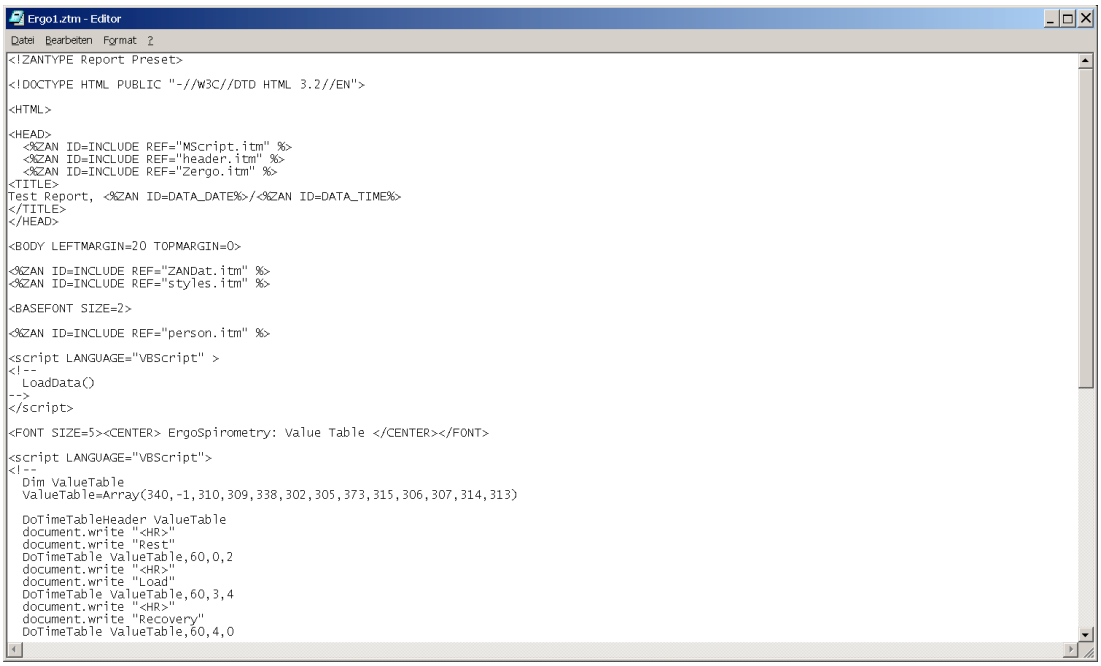
If you want to save the changes press the Yes button, else the changes will be abandoned and the old design of the report is restored again.

8.1.5.11 Disabled Options

If you use the edit file option, a html file is opened in the Notepad editor.



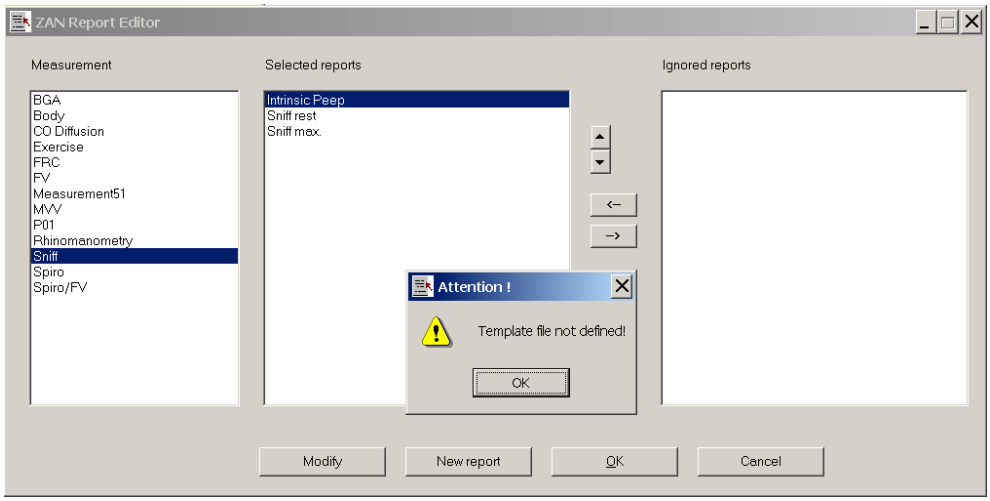
Edit file dialogue



Notepad with a raw template file open

This edit option is not intended to be used by unauthorised personnel. Please do not use this option. It will be disabled and removed in the next version.

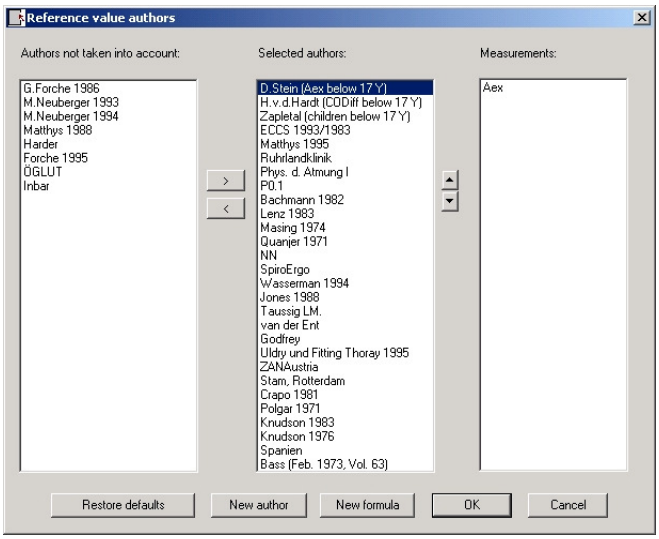
When you try to use the [New report] option, you will always get a "template file not defined" error message



This option has been disabled and will be removed in the next version. Please do not use this option.

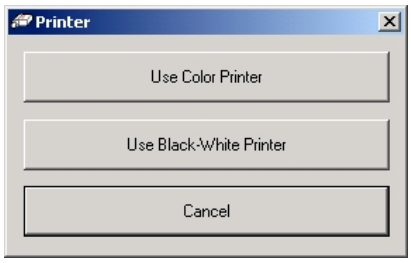
8.1.6 Reference Value Editor

You can define the use of the reference value tables of different authors according to your demands.



Add an author with [New Author] and a new equation with [New Formula]. You can also change the order in which the associated table is used. To activate and deactivate a particular table, use the arrow buttons on the left.

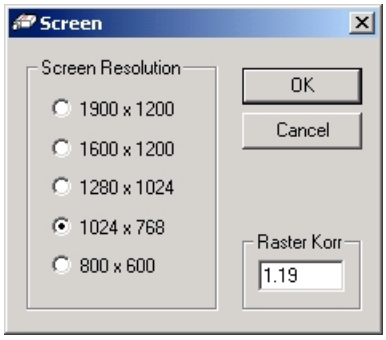
8.1.7 Printer Configuration



This dialogue box is used to define the printer type

Note: ZAN always uses the Windows® default printer

8.1.8 Screen resolution

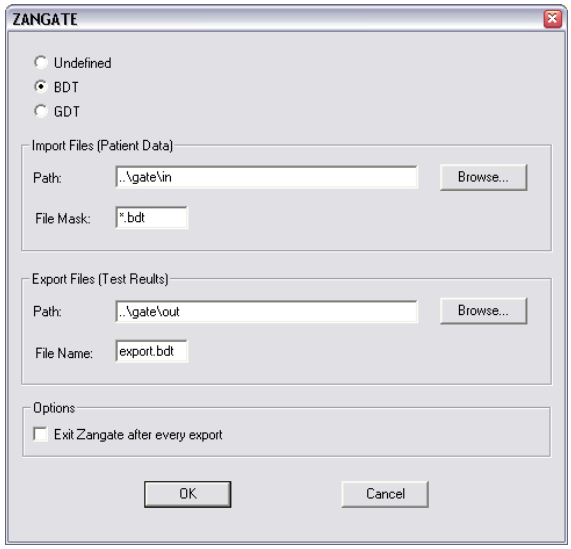


This dialogue defines the resolution of the computer monitor. Please select the appropriate setting. This setting will not change the basic Windows® setting, but is used to calculate the graphics and print outs internally.

Raster size, for ECG display for instance, is also defined in this dialog. The system detects correct values for this parameter automatically and should not be changed.

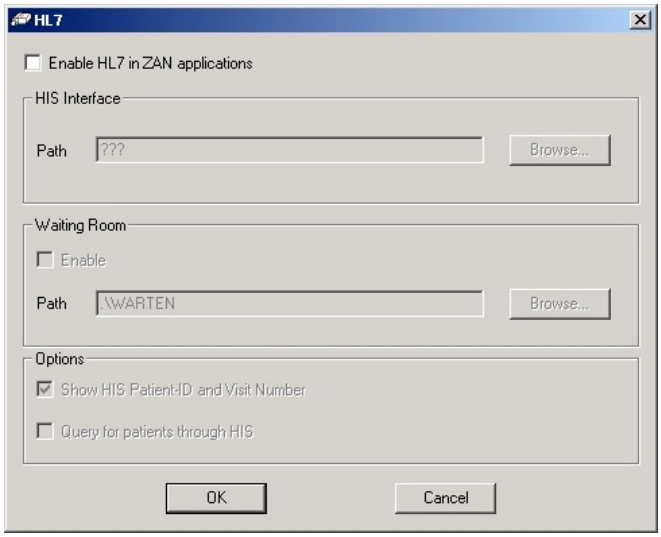
8.1.9 ZanGate (Optional)

When using the ZAN software in connection with a CPRS you can define basic communication parameters in this dialogue box. BDT and GDT are data formats used in Germany to perform standardised data exchange with remote systems.



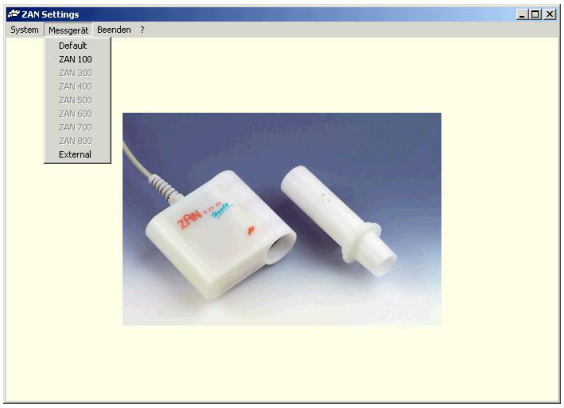
8.1.10 HL 7 (Optional)

This dialogue box is used to activate and configure HL7 communication with external hospital information systems.

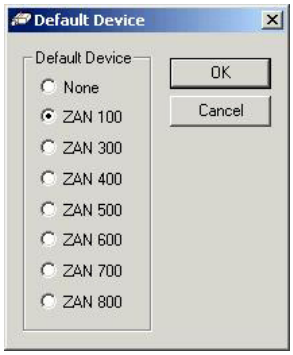


8.2 Device Settings

The „Device“ setting shows the following options.



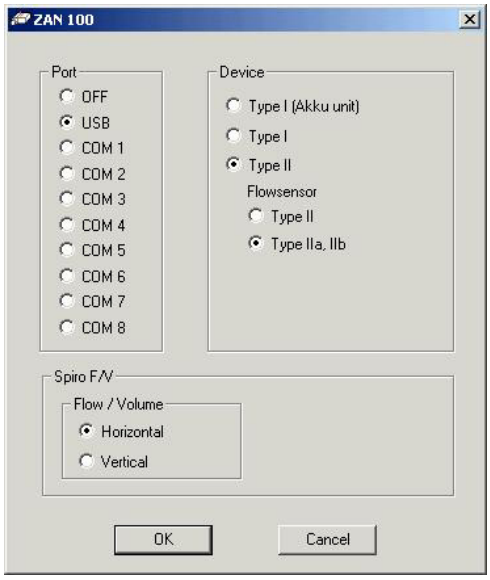
8.2.1 Default Device



Select your default device using this dialogue box. The default device must always be the main device of the system.

E.g. select ZAN100 when using a ZAN100USB device

8.2.2 Device specific settings

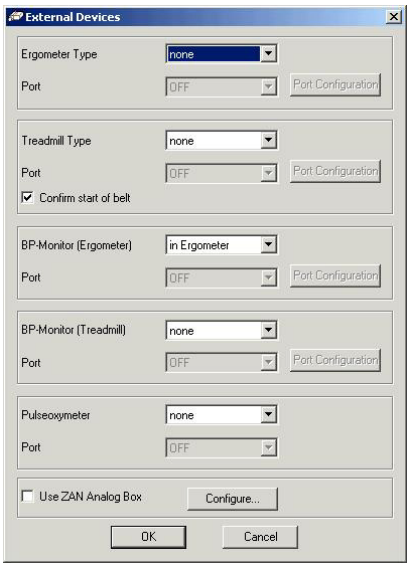


Select the port, where your ZAN100 device is connected to. With the ZAN 100 USB it is always the USB port.

Please do not change settings in the 'Device' segment. These settings should be changed by qualified personal only. Please refer to you dealer or the ZAN service, if you need to make changes here.

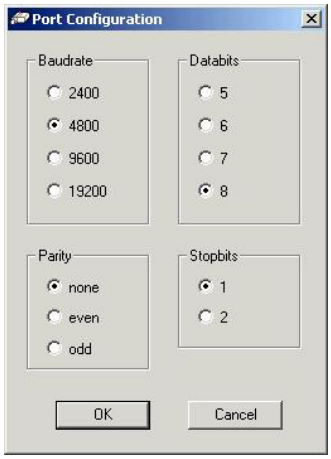
Spiro F/V toggles the display of the Flow/Volume chart between portrait and landscape.

8.2.3 External Devices



Select the type of external device. The device is activated when you change the type in the drop down box from 'none' to a different value. This will also activate the associated port dialogue box.

Select the port, where your external device is connected to.



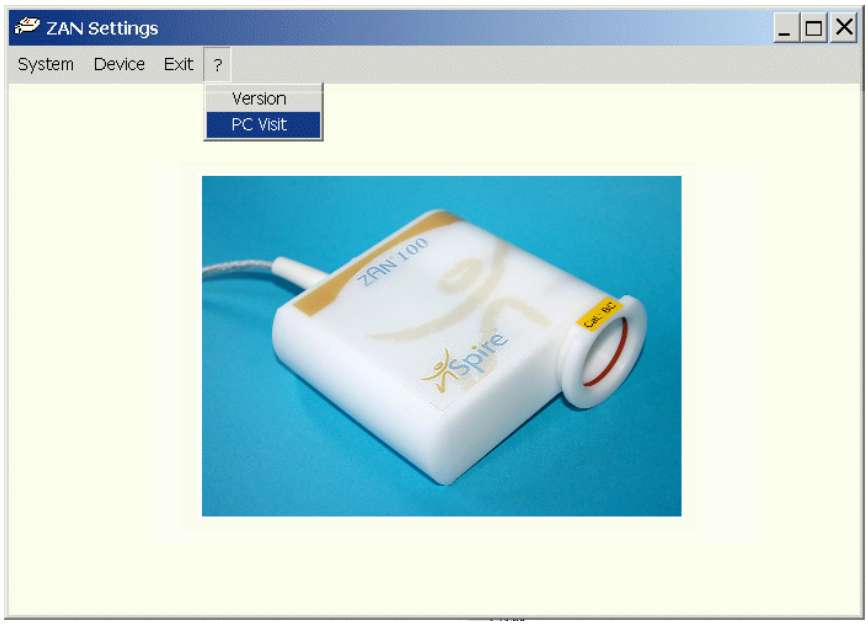
After selecting the port, you can set-up the corresponding port configuration by clicking on the [port configuration] button.

This dialogue allows you to define necessary parameters like baud-rate, data format, parity, and stop bits for a serial port for example.

Please refer to the manual of the external device to find the correct settings.

1.1.1 On line support

nSpire Health uses the remote control software "PC-Visit" for on line support. PC-Visit is not active during normal work and needs to be started on demand. To invoke PC-Visit, select the corresponding item from the "Settings" Menu like shown below.



For more information refer to the product documentaion of PC-Visit.

9 Safety, Maintenance, Service

9.1 General Security Information

We explicitly declare that the regulations in this manual are according to the MPG and the DIN EN 60601-1.
The particular regulations are not part of this manual.

Use of devices and software is exclusively reserved for medical diagnostic and therapeutical purposes. Only trained and experienced personal should be allowed to use the devices on patients.

If there is damage to a part or system due to misuse, VDE protection is broken. In this case disconnect the device from any external power and contact your ZAN service before any further use.

nSpire Health GmbH takes responsibility for security and reliability of the device only if:

- All changes, extensions, repair or other work is done exclusively by authorised personnel of the nSpire Health GmbH.
- Electrical installations of the room in which the device is operated conforms to VDE 0107.
- Operation of the device is done according to the instructions in the manuals.
- The instructions in the technical description have been observed carefully.

Caution:

Never operate medical devices of nSpire Health GmbH in an environment which is endangered by explosions.

Never extend cables or tubes without the explicit permission of nSpire Health GmbH.

In case of damage of current carrying parts or parts which have to carry weight, set the equipment out of order, disconnect all power cables and report to nSpire Health GmbH service or your local medical device technical department.

Make sure that all networking connections are equipped with indirect coupling.

Observe carefully the instructions in the "Disinfection" chapter.

The user is responsible for the correct use of disinfection and proper set-up of the equipment.

Electromagnetic Interference

Medical devices require special care concerning electromagnetic interference. All devices have to be installed and operated in accordance with the instructions and regulations provided with the equipment.

- Strong transmitters must not operate near the equipment.
- Portable HF devices (such as Mobiles for example) can possibly influence the functionality of devices. Avoid using such devices near nSpire equipment.
- The devices are tested up to a level of 3mV/m and should not be exposed to electromagnetic fields of a higher level.

- Do not operate the device near heavy current powerlines or devices.

9.2 Device specific Security Information

9.2.1 Flowhandy ZAN100 USB

The Flowhandy ZAN100 USB is part of all following devices.

Caution

The Flowhandy ZAN100 USB may only be operated in connection with peripherals which fulfil the DIN EN 60950 or DIN EN 60601-1 for medical equipment and have a valid CE certification. PC devices must comply with the minimum configuration standards explained in the technical description.

Office equipment according to DIN EN 60950 is not the same as medical equipment according to DIN EN 60601, therefore a minimum distance of 1.5 m between the patient and the device which does not follow DIN EN 60601-1 is required.

E.g. The medical device Flowhandy ZAN100 USB is in accordance with DIN EN 60601-1 but the PC is only DIN EN 60950. The Minimum distance between the patient and the PC must be at least 1.5 m, while there is no need to keep distance between the Flowhandy ZAN100 USB and the patient.

If this is not possible because of reasons such as small rooms etc. we strongly recommend the use of a ZAN system desk which provides indirect coupling for the complete equipment and fulfils the necessary requirements according to the medical product law.

9.2.2 ZAN500 Body Box

Caution

The ZAN500 Body Box requires the ZAN system desk for safe and legal operation.

Do not pull the door downwards while it is open. This could cause the whole chamber to fall over.

The patient must know how to open the door of the chamber from inside by his/herself.

Never leave the patient alone inside the chamber without supervision.

All connections and cables between the chamber and the system desk are purposefully short so as to avoid stumbling over them. Make sure all staff are aware of the cables to avoid any accidents.

9.2.3 CO Diffusion (ZAN300) and FRC (ZAN310 FRC Helium) Options

Caution The ZAN300 as well as the ZAN 310 FRC Helium must use the specially designed ZAN system desk for safe operation.

Extension of any tube will cause inaccurate results during measurement and is therefore, strictly forbidden.

Tubes for CO diffusion and FRC measurement must not be bent.

Avoid sudden major changes of environmental parameters such as temperature for example. This will create faulty measurement and could damage the analysers.

9.2.4 ZAN600 USB

Caution The ZAN600 USB may only be used in connection with devices which comply at least with the DIN EN 60950 Norm and have a valid CE certification.

The devices must not be operated in an environment which is endangered by explosions.

The ZAN600 USB must be operated with the original power supply or with the built in power supply of the ZAN system desk, which complies with DIN EN 60601-1.

9.2.5 ZAN 800 ECG

Caution The ZAN800 ECG may only be used in connection with devices which comply at least with the DIN EN 60950 Norm and have a valid CE certification.

The devices must not be operated in an environment which is endangered by explosions.

The ZAN800 ECG must be operated with the original plug-in power supply which is DIN EN 60601 certified.

The ZAN800 ECG must be cleaned and disinfected in accordance to the instructions of the user manual. The user is responsible for the correct application.

Warning! During the test a physician must be present and a defibrillator must be available!

The load test must be stopped immediately, when the heart frequency of the patient reaches the upper threshold or, if the ECG shows abnormalities.

Defibrillator Protection

The ZAN800 ECG has a built in defibrillation protector, but every cable from the patient to the device must be protected with a 4700 Ohm resister.

9.3 Using customer supplied equipment

The devices built by nSpire Health GmbH and the nSpire system cart together form a unit which is fully compliant to German MPG. These sets are manufactured in a way that allows connection to a PC, which is not protected by the security system built into the nSpire system cart.

If the nSpire devices are to be connected with the PC of a different provider, consider the following instructions:

1. The PC has to meet the minimum requirements defined in the technical description of the software manual.
2. The PC has to meet the DIN EN 60950 norm and have a valid CE certification. If not, the patient could possibly get an electric shock when touching the device, because of unequalised ground potential differences between the PC frame and the ZAN device.
3. The distance between the patient and the PC during operation must be more than 1.5 m.
4. Within a distance of less than 1.5 m, no nonmedical device may be associated with a medical device.
5. Within 1.5 m distance to the patient no network connections may be installed without a 4kV proof disconnection (indirect coupling).

Caution Mains operated devices, which comply to DIN EN 60950 cannot be compared to devices complying to DIN EN 60601-1 for medical devices. For this reason, medical devices are equipped with galvanic disconnectors (indirect coupling) which disconnect the medical device from the PC System according to well defined rules. But a minimum distance of 1.5 m from the device to the patient is necessary to keep the effectiveness of the disconnectors.

If this is not possible, nSpire Health GmbH strongly recommends the use of the nSpire system cart, which is able to completely disconnect the PC from the mains.

9.4 Connecting Devices

Power cables and data connections should be fastened in a way, that they cannot disconnect accidentally. Always check if the device is built in accordance with the regulations in the corresponding law.

E.g. In Germany a maximum overall discharge defined in DIN EN 60601-1 must not be exceeded, when additional devices are connected.

9.5 Special Precautions With Treadmills

Treadmills use very powerful engines. Only treadmills designed according to the regulations for medical products should be used.

Always position the treadmill so that if the patient falls accidentally, he/she does not encounter injuries.

If the patient falls, he/she will be moved backwards. The place behind the treadmill should therefore be free from any objects/equipment. We recommend placing padding on the walls behind the treadmill.

Depending on the patients condition, a special safety belt might be necessary to prevent the patient from falling.

On any malfunction, such as a power failure, the patient must leave the treadmill immediately, because some treadmills accelerate on recovery (skipping the normal start programme) and this may cause the patient to fall off.

Also a sudden stop of the band must be avoided because it could make the patient fall onto or over the front of the treadmill.

Read the safety information by the treadmill manufacturer carefully.

9.6 Symbol Definitions

	If a part or product is marked with this symbol, it is compliant to DIN EN 60601-1, Type BF.
	If a part or product is marked with this symbol, it is compliant to DIN EN 60601-1, Type B.
	If a part or product is marked with this symbol, it is compliant to DIN EN 60601-,1 Type BF with additional defibrillator protection. This means, the device is isolated from the mains and has a built in protection against over voltage.
	Caution! Read the accompanied manuals.
	device of protection class II.
IPX0	Not protected against liquid.
	protective conductor connector

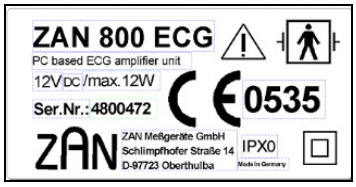
This product is compliant to regulations for medical products 93/42/EWG and German law MPG.

The number describes the institute which performed the CE certification.

In this example it is the Eurocat GmbH institute in Darmstadt.

If necessary, nSpire Health GmbH is able to present the corresponding documents, which allow application of this symbol on the device.

Typical Product Label



The serial-number is defined as:

The 1. number is the year. (The 4 means 2004 for example).

Numbers 2-4. define the product code (800.in this example)

9.7 Maintenance Information

A8.2.1 Gas Container Valves

Caution:

Do not open the valve to the absolute ending and leave it in this position. The valve might be blocked irreversibly by the internal pressure of the container. Always take one half turn back, when the opening end has been reached.

9.7.1 Pressure Reducer

Pressure reducers need periodical maintenance. Please refer to the manufacturers manual for the correct maintenance intervals.

9.7.2 Flow Sensor

Lifetime:

The Flow Sensor is directly exposed to the patients breath, disinfective agents and a permanent change of humidity and temperature. That makes it impossible to guarantee a minimum lifetime. The typical lifetime of a Flow Sensor is about 5 years according to customer reports.

Calibration:

Calibration is recommended after every disinfection or after exchange of the Flow Sensor.

Calibration can be performed by the customer using the 1L calibration syringe. The syringe is available from nSpire Health GmbH. The necessary software is already included in the standard software package.

If the customer does not want to calibrate the Flow Sensors, they can send them to nSpire for calibration.

If the calibration results show significant deviations from the reference values, the Flow Sensor should either be replaced or re-encoded by nSpire.

Check:

There are two criteria to determine if a Flow Sensor produces correct results:
1. Raw Inspection of the membranes. If the membranes are mechanically damaged, the Flow Sensor should not be used.

2. Precise Calibration.

Deviation in/ex > 6% or

Deviation 1.00 <> 10%

The Calibration Software provides automatic detection of deviation and will give a warning message. Additionally, the correction coefficients cannot be saved.

9.7.3 Flowhandy ZAN 100 USB

Lifetime:

The lifetime of a Flowhandy ZAN100 USB depends strongly on usage and mechanical strain. When used carefully, lifetime is only limited by the lifetime of the sensors and the electronic parts inside.

The manufacturer of the Pressure Sensor guaranteed a maximum error of less then ± 0.2% over 1 million maximum pressure changes. Under normal conditions the maximum range will never be reached. A typical flow measurement produces about 20 changes in pressure. If a physician uses this device frequently, and about 50 patients per day are tested, this would approximately define a minimum lifetime of 5 years for the Pressure Sensor.

Calibration:

Calibrating the Flow Sensor simultaneously performs a calibration of the Flowhandy.

Maintenance:

nSpire recommends a technical check-up after ca. 1000 measurements or after 12 months of use (which ever happens first).

The service is done at nSpire Health GmbH and includes tests of the following parameters:

- Tightness
- Mechanical condition
- Measurement precision
- Data communication
- Linearity

The customer will receive a written test report with all results of the service from nSpire Health GmbH.

The customer can also check mechanical conditions as well as calibrate the system with the 1L Calibration Syringe, which is available from nSpire Health GmbH.

9.7.4 ZAN500 Body Box

Lifetime:

The lifetime of the ZAN500 Body Box depends on how the device is used and how much mechanical strain the device has had to endure. When used carefully, lifetime is only limited by the lifetime of the sensors and the electronic parts inside.

Under normal conditions a lifetime of 8 years or more is usual.

Calibration:

Calibration of the bodyplethysmograph includes volume calibration. The latest detected calibration factors are saved and used by the software

We recommend calibrating the bodyplethysmograph once per day.

Please refer to the corresponding manual, chapter 'Calibration' for details.

Caution:

nSpire Health GmbH recommends a service of the system by nSpire Service Dept, once a year.

The customer will receive a written test report with all results of the service and the calibration values from nSpire Health GmbH.

9.7.5 CO-Diffusion Option (ZAN300)

Lifetime:

The lifetime of the CO-Diffusion option is limited by the CO/CH4 analyser. Depending on how often it is switched on and off, it lasts between 3 to 6 years.

Another wearing part is the suction pump. The manufacturer guarantees a minimum of 3000 working hours.

Since the pump is only working while the CO diffusion measurement is running (which last about 1 minute,) the pump will last approx. 120 000 measurements

Calibration:

A calibration of the CO-diffusion option is not necessary if the device is sent in to nSpire maintenance for a service at regular intervals.

Warning:

nSpire Health GmbH strongly recommends a service of the CO-diffusion option by nSpire **once a year**.

The customer will receive a written test report with all results of the service and the calibration values from nSpire Health GmbH.

9.7.6 FRC Helium Option (ZAN310)

Lifetime: The lifetime of the FRC Helium option is limited by the lifetime of the He-analyser. Depending on how often the analyser is switched on and off, a lifetime between 3-6 years is usual.

Another wearing part is the suction pump. The manufacturer guarantees a minimum 3000 working hours.
Since the pump is only working when the measurement is running (which lasts about 1 minute) the pump will last about 120 000 measurements.

Calibration: Calibration is not necessary. Regular maintenance ensures proper functioning of the option.

Leak Tests: Leak free equipment is fundamental to obtain valid results.

The procedure of the leak test is described in the corresponding manual. The test should be performed at least once per week and it must be performed when the absorber granules have been changed.

Absorber: The absorber granules remove the carbon dioxide from the exhaled air. The capacity is limited and it needs regular replacement. nSpire recommends replacing the granules every 90 minutes of breathing.

Please refer to the option manual for more details.

Maintenance: nSpire Health GmbH strongly recommends a Service of the ZAN310 FRC Helium option by nSpire **once per year**.

The customer will receive a written test report with all results of the service from nSpire Health GmbH.

9.7.7 Ergo Flow Sensor

Lifetime:

The Flow Sensor is directly exposed to the patients breath, disinfective agents and a permanent change of humidity and temperature. That makes it impossible to guarantee a minimum lifetime. The typical lifetime of a flowsensor is about 5 years according to customer reports.

Calibration:

Calibration is recommended after every disinfection or after exchange of the Flow Sensor.

Calibration can be performed by the customer using the 1L calibration syringe. The syringe is available from nSpire Health GmbH. The necessary software is already included in the standard software package.

If the customer does not want to calibrate Flow Sensors, they can send them to nSpire for calibration.

If the calibration results in unacceptable deviations from the reference values, the Flow Sensor should either be replaced or re-encoded by nSpire.

Check:

There are two criteria to determine if a Flow Sensor produces correct results:
1. Raw inspection of the membranes. If membranes are mechanically damaged, the Sensor is unusable
2. Precise Calibration:

   Deviation in/ex > 6% or

   deviation 1.00 <> 10%

The Calibration Software provides automatic detection of deviation and gives a warning message. Additionally correction coefficients cannot be saved.

ZAN600 USB

Lifetime:

The lifetime of the ZAN600 USB system depends strongly on usage, strain and maintenance.

One of the main factors is the lifetime of the analysers.

A lifetime of at least 5 years can be expected under normal conditions and if properly used.

Caution:

The ZAN600 USB is a medical measurement device, built according to strict legal regulations of the German MPG. Chapter 5 of the regulations demands regular supervision of the measurement precision.

nSpire Health GmbH recommends supervision by either nSpire Health GmbH or another authorised institution once a year.

In addition the user is also advised to follow the regulations concerning correct usage and proper handling.

Maintenance:

A service at nSpire Health GmbH includes tests of the following parameters:

- Leaks
- Mechanical condition
- Measurement precision
- Data communication
- Linearity

The customer will receive a written test report with all results of the service from nSpire Health GmbH.

The customer is also able to check mechanical conditions and connectivities, as well as calibrate the system with the Calibration Syringe using special testgas, which is available from nSpire Health GmbH.

9.7.8 ZAN 800 ECG

Lifetime: The lifetime of the ZAN 800 ECG system depends on usage, mechanical strain and maintenance.
Under normal conditions, a lifetime of more than 8 years may be expected.

Maintenance: The ZAN 800 ECG is a medical measurement device, built according to strict legal regulations of the German MPG. Chapter 5 of the regulations demands regular supervision of the measurement precision.

nSpire Health GmbH recommends supervision by either nSpire Health GmbH or another authorised institution once a year.

In addition the user is also advised to follow the regulations concerning correct usage and proper handling.

9.8 Service Contracts

nSpire Health GmbH offers Service Contracts, individually customised to meet the particular needs of our customers. This assists our customers correct maintenance of their nSpire products which in turn provides optimum use and reliable results.

Please contact our Sales Representatives or nSpire Health GmbH directly for more information.

9.9 Customer Service

nSpire Health GmbH co-operates very closely with our associated dealers. Together we endeavour to provide an optimum service for our customers.

Usually your dealer has good knowledge of your particular needs concerning hard and software of your nSpire products. This makes them the best point of contact to ask for assistance. They will be able to give competent answers and quick support.

Our Service Department can also be contacted directly

at :

nSpire Health GmbH
Schlimpfhofer Str. 14
D-97723 Oberthulba

Phones:

Central:	+49 (0) 9736 / 81 81-0
Customer Service	+49 (0) 9736 / 81 81-17 or -27
Sales - Germany	+49 (0) 9736 / 81 81-30
Sales - International	+49 (0) 9736 / 81 81-14
Fax	+49 (0) 9736 / 81 81-20

9.10 Warranty

9.10.1 Limited Warranty

The warranty covers defective materials and manufacturing for one year. Within this time nSpire will replace or repair defective parts or products at no charge (except shipping costs).

9.10.2 Exclusions

The warranty does not cover damages caused by the following reasons:

- Negligent handling
- Improper maintenance
- Third party software or hardware connections
- Unauthorised changes or abuse
- Neglecting storage regulations
- Operation outside of the allowed environmental conditions
- Incorrect voltage
- Mechanical damage of the Flow Sensor
- Use of unpermitted disinfection agents
- Hardware damage caused by software

The warranty starts on the day of delivery to the customer.

9.10.3 Terms Of Warranty

The given Warranty exclusive. There will be no other warranty or extensions to this warranty, neither written nor verbally given. Every other warranty concerning common quality or aptitude is also limited to a one year period.

Some states do not allow the limitation or exclusion or liability for incidental or consequential damages, so the above limitation or exclusion may not apply to you.

9.10.4 Maintenance within the warranty period

The devices must be shipped in original packaging to avoid damage during transportation. The customer is responsible for damages caused during shipping due to improper packaging.

10 Waste Management, Recycling

10.1 Electronic Components

Some products contain electronic components. To avoid environmental risks or hazard, waste management of these components underlies particular regulations depending on local laws. These regulations may vary widely from state to state

10.2 Mechanical Components

Inside the mechanical units and accessories of nSpire devices are, as far as possible, only materials used, which can be recycled.

Most used materials are coated aluminium and POM (Polyoxymethylen, Ultraform H2320 from BASF). Refer to the waste management regulations of your state or county concerning these products. There is no need to send these products back to nSpire, they can be disposed of by the customer.

nSpire Health GmbH avoids single use components where ever possible. Only parts which can be separated and disinfected easily when contaminated, are used.

In principal only unbleached paper and cardboard is used for packing.

Packing material can be disposed of like ordinary waste.

10.3 CO_2 Absorbing substances

The absorber granules (absorbence) must be handled according to the local regulations. If in doubt, ask the waste management department of your county administration for correct information.